UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 29, 2002

MEMORANDUM:

SUBJECT: **Oxyfluorfen.** Revised Human Health Risk Assessment. HED Chapter for the Reregistration Eligibility Decision (RED) Document. Reregistration Case No. 2490. Chemical No.111601. DP Barcode D281831.

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Please find attached the revised Human Health Risk Assessment for the oxyfluorfen Reregistration Eligibility Decision Document (RED). The assessment was revised to address comments raised during the 60 day public comment period. This assessment reflects current HED policy and supercedes the previous HED Human Health Assessments dated September 20, 2001 (DP Barcode D250186) and December 10, 2001 (D279694). The HED chapter includes the Hazard Assessment from Kit Farwell, Reregistration Branch I (Attachment 1), Product and Residue Chemistry Assessments and Dietary Exposure Analysis from Jose Morales, Reregistration Branch 3 (Attachment 2), and the second revised Occupational and Residential Exposure Assessments from Timothy Dole, Reregistration Branch 1 (Attachment 4). Information was also drawn from the 04/23/01 HIARC memorandum (HED Doc. No. 014549), the EFED's Water Resource Assessment, the FQPA Safety Factor Committee memorandum (4/30/2001) and the oxyfluorfen incident report (4/3/2001). This risk assessment or its components have been evaluated within HED by the following peer review committees: HIARC, FQPA SFC, ChemSAC, ExpoSAC, DE SAC, and RARC, and it includes the comments and recommendations of the aforementioned committees.

OXYFLUORFEN

HED'S HUMAN HEALTH RISK ASSESSMENT

1.0 EXECUTIVE SUMMARY

The Health Effects Division (HED) has conducted a human health risk assessment for the active ingredient **oxyfluorfen** for the purpose of making a reregistration eligibility decision. HED evaluated the toxicology, residue chemistry, and occupational/residential exposure databases for oxyfluorfen and determined that the data are adequate to support a reregistration eligibility decision.
Oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] is a broad spectrum pre- and postemergent herbicide used to control annual broadleaf and grassy weeds in corn, cotton, soybeans, fruit, nut trees, and ornamentals. It is registered for residential use as a spot treatment to kill weeds on patios, driveways and similar areas.

Oxyfluorfen is a diphenyl ether herbicide structurally related to lactofen and acifluorfen. The diphenyl ether herbicides act by inhibiting protoporphyrinogen oxidase which is the second-to-last enzyme in chlorophyll biosynthesis in plants and in heme synthesis in animals. The diphenyl ethers are also oncogenic in rodents.

Oxyfluorfen and other herbicidal inhibitors of protoporphyrinogen oxidase are being evaluated by the Environmental Fate and Effects Division (EFED) and the Office of Research and Development (ORD) of EPA for possible phototoxicity based on reports of porphyrin accumulation in test animals. Since the biosynthesis of heme is inhibited by oxyfluorfen, there is the possibility that porphyrin precursors of heme could accumulate in the skin and be activated by light and cause toxicity. There have so far been no indications that oxyfluorfen does cause phototoxicity.

It should be noted that older toxicity studies with oxyfluorfen used technical material of approximately 71% or 85% purity. The newer toxicity studies used a technical material of approximately 98% purity, which is the basis for the current registrations of oxyfluorfen. The two current registrations for technical material are for 97.4% and 99%. The newer technical material has qualitatively similar impurities to the older technical material, but in reduced concentrations. New studies with the current 98% product that were submitted and evaluated were: subchronic toxicity in rats, developmental toxicity in rats and rabbits, a battery of mutagenicity studies, and a battery of acute studies. Toxicity was less severe for studies with the 98% product than for the 71% product.

When there were studies with both the new and old technical material, preference for an endpoint for risk assessment purposes was given to the newer, 98% technical material (current registrations). The toxicology studies described in this document had doses adjusted for percent active ingredient and/or for analytical concentrations determined in the diet.

Oxyfluorfen is of low acute toxicity and is in toxicity category IV for acute oral, dermal, and inhalation toxicity. It is a slight eye and dermal irritant and is not a dermal sensitizer.

Toxicity was similar for subchronic and chronic rat, mouse, and dog studies in both sexes. Although oxyfluorfen inhibits heme synthesis, the resulting anemia was generally mild. A microcytic anemia with a decreased hematocrit, small erythrocytes, and normal red blood cell count was described in the 1997 subchronic rat study with the current 98% registration. In other words, the red blood cell count was normal in this study, but the red blood cell mass was decreased because of the small size of the red blood cells, presumably because of inhibition of the protoporphyrinogen oxidase enzyme. The anemia was generally mild in other studies, with varying hematologic abnormalities described in the rat, mouse, and dog studies.

Mild liver toxicity was described in the 1997 subchronic rat study with the current 98% registration. Increased liver weight was accompanied by very slight increases in liver enzyme activities and minimal microscopic changes. Similar effects also occurred in the other subchronic and chronic rat, mouse, and dog studies. There were typically few histopathological lesions seen in the liver, although hepatocyte necrosis did occur in the mouse and dog studies.

Renal toxicity was most severe in the 2-generation reproduction study in rats, in which pelvic mineralization occurred. Other subchronic and chronic rat studies had other indications of renal toxicity, increases in organ weight and occasional histopathological observations. Treatment-related mortality occurred in the subchronic mouse study, the reproduction study, and developmental studies in rats and rabbits. Other toxicological changes included excessive lacrimation in the chronic dog study and increases in urine volume and water consumption in the 1997 subchronic rat study.

Developmental studies with the current 98% technical material found no developmental toxicity in rats whereas an increase in late resorptions occurred in the rabbit study (principally in 1 litter). A developmental study in rats with the older 71% technical material found increased early resorptions, decreased fetal weight, and increased incidence of fetal visceral and skeletal variations and malformations. A developmental study in rabbits with formulation manufactured from the older technical material found increased early resorptions and decreased litter size. A reproduction study with 71% technical material reported decreased live pups per litter and decreased pup body weights.

The newer technical material (96-99% a.i.) was tested in 12 genetic toxicology studies, which included assessments of gene mutation, chromosomal aberrations, and DNA damage. All assays were negative, except for one Ames assay which was positive only at high, insoluble levels. A subsequent Ames assay with 96% material was negative. The older 72% technical material and a polar fraction were tested in eight genetic toxicology studies. Both Ames assays and a mouse lymphoma study were positive for the 72% technical material. The polar fraction of the 72% technical material was also positive in an Ames assay.

Oxyfluorfen is classified as a category C, possible human carcinogen based upon combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. The Cancer Peer Review Committee recommended a linear, low dose extrapolation for human risk assessments, with a Q_1^* of 7.32×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

Based upon the developmental and reproductive toxicity studies reviewed, there does not appear to be any increased susceptibility in animals due to pre- or postnatal exposure to oxyfluorfen. Although neurotoxicity studies were not performed, there was no indication of neurotoxicity in the submitted studies or in the published literature. A developmental neurotoxicity study was not required. The FQPA Safety Factor Committee determined that for oxyfluorfen, the 10-fold safety factor for the protection of infants and children should be reduced to 1X.

The HED Hazard Identification Assessment Review Committee (HIARC) selected endpoints for human health risk assessments. No appropriate endpoint was identified for acute dietary or short-term incidental oral endpoints because no adverse effects reflecting the cause produced by a single dose was identified. Accordingly, no acute dietary or short-term incidental risks were assessed. Acceptable dermal and inhalation studies were not available, consequently oral endpoints were selected for these exposure routes. In general, the quality of the toxicity studies for oxyfluorfen provided reasonable confidence in the toxicity endpoints and doses selected for risk assessment. All doses for risk assessment purposes were assessed along with the uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variability. An additional uncertainty factor of 3X was applied to intermediate-term exposures because the dose was derived from the LOAEL. The specific doses and endpoints are summarized as follows:

- Chronic dietary - NOAEL = 3.0 mg/kg/day based on liver toxicity occurring in mice and dogs. The LOAEL was 33 mg/kg/day in the mouse carcinogenicity study and 18.5 mg/kg/day in the chronic dog study.

- Cancer - $Q_1^* = 7.32 \times 10^{-2}$ $(mg/kg/day)^{-1}$ based on combined hepatocellular adenomas and carcinomas in males in a mouse carcinogenicity study. Oxyflourfen is classified as a Category C possible human carcinogen .

- Short-term dermal and inhalation - NOAEL =30 mg/kg/day based on abortions and clinical signs (loose feces, thin build) found at the maternal LOAEL of 90 mg/kg/day in a developmental rabbit study.

- Intermediate-term incidental oral, dermal and inhalation - LOAEL = 32 mg/kg/day based on liver toxicity and anemia found in a 90-day mouse study. Note: an oral endpoint was used for dermal and inhalation exposure.

- Long term dermal and inhalation - NOAEL = 3 mg/kg/day based on liver toxicity occurring in dogs and mice. The LOAEL was 33 mg/kg/day in the mouse carcinogenicity study and 18.5 mg/kg/day in the chronic dog study.

- Dermal exposure assessments will use an absorption factor of 18% of oral exposure. Inhalation exposure assessments will use an absorption factor of 100% of oral exposure.

The oxyfluorfen dietary risk analyses reflect highly refined exposure assessments. Anticipated residues (ARs) and percent crop treated information were incorporated. ARs were calculated using either U.S. Department of Agriculture Pesticide Data Program (USDA PDP) monitoring data or field trial data. Both data sets are consistent in that they show essentially all non-detectable residues with the same limit of detection (0.01 ppm).

Chronic dietary risk is calculated by using average consumption and residue values. A risk estimate that is less than 100% of the chronic Population Adjusted Dose (PAD) does not exceed HED's level of concern. The PAD is the Reference Dose (RfD) divided by the FQPA safety factor. Since the FQPA safety factor for oxyfluorfen is reduced to 1X, the RfD and the PAD are equivalent.

Chronic risks calculated using a chronic PAD of 0.03 mg/kg/day were low (<1% cPAD) for all population subgroups of concern. Cancer risks were also not of concern with an estimated lifetime risk to the general population of 3.8×10^{-7}. Because detectable residues of oxyfluorfen were not found in food, a sensitivity analysis assuring no residues in samples with oxyfluorfen at less than the limit of detection (LOD) would result in essentially no dietary risks.

The EFED provided the drinking water assessment using simulation models to estimate the potential concentration of oxyfluorfen in ground and surface water. Limited surface and ground water monitoring data are available for oxyfluorfen but these data are not adequate to perform a quantitative drinking water assessment. With respect to the exposure in surface water, conservative Tier II (PRZM-EXAMS) modeling was done indicating that oxyfluorfen estimated environmental concentrations (EECs) in surface water are not likely to exceed 23.4 ppb for peak (acute) exposure, 7.1 ppb for mean (chronic) exposure and 5.7 μg /L for the 36 year annual mean concentration (used for cancer assessment). Using the SCI-GROW model to estimate concentrations of oxyfluorfen in ground water yielded low EECs for both acute and chronic exposure at 0.08μg/L.

Oxyfluorfen has registered uses in the residential environment by homeowners to kill weeds on patios, driveways and similar surfaces. Based on this use pattern, HED has determined that exposure to homeowners would result in short-term exposure. Non-cancer risks calculated for four residential exposure scenarios yielded Margins of Exposure (MOEs) of 8500 to 171,000 which exceeded the target MOE of 100 and were, therefore, not of concern to HED. The cancer risks for all of the scenarios were less than 1×10^{-6} and were, therefore, also not of concern.

There are no concerns of post application residential exposure because residential uses are limited to spot treatments which do not include broadcast application to lawns. In addition, the label states that oxyfluorfen kills grass.

In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures from pesticide residues in food and other exposures including drinking water and non-occupational exposures, e.g., exposure to pesticides used in and around the home (residential). Risk assessments for aggregate exposure consider short-, intermediate- and long term (chronic) exposure scenarios considering the toxic effects which would likely be associated with each exposure duration. There are residential uses of oxyfluorfen; therefore, the considerations for aggregate exposure are those from food, water, and residential uses. Since conservative modeling was done to estimate concentrations in drinking water, Drinking Water Levels of Comparison (DWLOCs) were calculated. A DWLOC is a theoretical upper concentration limit for a pesticide in drinking water based on how much of the PAD remains once exposures in food and in the home have been estimated and subtracted. For oxyfluorfen, only chronic, short-term, and cancer DWLOCs were calculated since an acute endpoint was not selected and no intermediate- term residential uses were identified.

Upon comparison of the chronic DWLOCs with the EEC for oxyfluorfen, surface and groundwater concentrations were less than the DWLOCs for all populations. Consequently, there was no chronic concern for drinking water from surface or groundwater sources.

The cancer DWLOC was essentially zero because when aggregated, the lifetime risk from food and residential exposure alone exceeded HED's level of concern. It should be noted that surface water EEC's exceed the DWLOC, even when the entire risk cup is reserved for water.

Surface and ground water EECs are below the short-term DWLOCs for oxyfluorfen. Consequently, there is no short-term exposure concern for drinking water from surface or groundwater sources.

Occupational exposure assessments were also conducted for oxyfluorfen. For occupational risk analysis, twenty-one handler/applicator scenarios were identified for oxyfluorfen. Analyses for handler/applicator exposures were performed using Pesticide Handlers Exposure Database (PHED) data and data from an exposure study which involved broadcast spreader application of a granular pesticide to lawns. Single layer Personal Protective Equipment (PPE) (which includes gloves, but not respiratory protection) is sufficient to achieve MOEs of greater than 490 for all of the handler/applicator scenarios. The cancer risk for all of the custom handler/applicator scenarios (thirty days exposure per year) are less than 1×10^{-4} with single layer PPE. Additional levels of PPE cause a modest risk reduction and six of the scenarios remain above 1×10^{-5} with maximum PPE. The use of engineering controls reduces the cancer risk to less than 1×10^{-5} for all scenarios. Cancer risks for all the private grower scenarios (5 or 10 days exposure per year) are 6.8×10^{-6} or less with single layer PPE. Most of private grower cancer risks are 1×10^{-6} or less with single layer PPE or with engineering controls. The PPE requirements as listed on the labels range from baseline to double layer with most of the labels requiring waterproof or chemical resistant gloves. Only one of the labels (Scotts OHII) requires respiratory protection.

HED determined that workers may be exposed to oxyfluorfen upon entering occupational areas previously treated with oxyfluorfen to perform specific work activities (e.g., scouting, irrigating, hand weeding). It was determined that re-entry workers would only have post-application exposure following applications of oxyfluorfen to conifer seedlings, conifer trees, and bulb vegetables because phytotoxicity to other commodities precludes foliar application. Although a Dislodgeable Foliar Residue (DFR) study was submitted for conifer seedlings, HED noted several serious deficiencies. An attempt was made to account for these deficiencies by applying correction factors; however, the data indicate faster dissipation rates than the default value of 10%. Consequently, MOEs were calculated two ways for conifer seedlings and trees using both the default assumptions and the DFR study. This DFR study was used to calculate risk for a possible interim regulatory decision. However, confirmatory data are required. MOEs for treatment of bulb vegetables were calculated based on default initial deposition and dissipation values.

The MOEs for non-cancer risks were 3700 or above for treatment of bulb vegetables on day zero and are not of concern for short- or intermediate-term exposures. The short-term MOEs for treatment of conifers ranged from 93 to 560 on day zero using default values with the highest exposure task being Christmas tree shearing. The short-term MOE for shearing rises to100 on DAT 1. The intermediate- term MOE shearing was 230 on day zero and approached 300 on DAT 1 if study data are used or in 3 days if the default dissipation value is used.

The Agency has defined a range of acceptable occupational cancer risks based on a policy memorandum dated August 14, 1996, by then Office of Pesticide Programs Director Dan Barolo. This memo refers to a predetermined quantified "level of concern" for occupational carcinogenic risk. Risks that are 1×10^{-6} or lower require no risk management action. For those chemicals subject to reregistration, the Agency is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protection are warranted as is commonly applied with noncancer risk estimates (e.g., additional PPE or engineering controls). Carcinogenic risks that remain above 1.0×10^{-4} at the highest level of mitigation appropriate for that scenario remain a concern.

The cancer risks for commercial re-entry workers working with bulb vegetables is 1.0×10^{-5} on day zero and declines to less than 1.0×10^{-6} in 23 days. The cancer risks for private growers working with bulb vegetables is less than 1×10^{-5} on day zero and declines to less than 1×10^{-6} in 12 days. The cancer risk for both private grower and commercial worker Christmas tree shearing exceeds 1×10^{-4} on DAT zero while the other Christmas tree scenarios are less than 1.0×10^{-4} on DAT zero. The risk for shearing declines to less than 1×10^{-4} in 1 day if study dat is used or in 4 to 14 days if the default value is used. The cancer risks for the conifer seedling scenarios are less than 1×10^{-4} on day zero for both private growers and commercial workers. These risks decline to less than 1×10^{-6} in 4 to 6 days if study data is used or in 30 to 41 days if the default value is used. The typical oxyfluorfen application rate for tree rows in North Carolina is 0.375 lbs ai/acre which is less than the label rate of 1.0 to 2.0 lbs ai/acre. Oxyfluorfen is used at this rate for “chemical mowing” to inhibit weed growth while maintaining some ground cover to prevent erosion. Additional calculations were performed using this rate indicating that the MOEs were above 300 on Day zero while the cancer risks were below 1.0×10^{-4} after one to five days of dissipation.

Although the oxyfluorfen databases were substantially complete, confidence in several areas of the risk assessment would improve with more data. The dermal toxicity study is classified as unacceptable and is a data gaps. Data which describes the frequency and timing of re-entry worker post-application exposures and acceptable DFR data for conifers would also be beneficial in assessing risks to workers. Moreover, the number of days of postapplication exposure per year was not known and the standard values of 10 days per year for private growers and 30 days per year for commercial workers was used as a screen. These values are probably conservative because oxyfluorfen is typically applied only a few times per year. It is also understood that oxyfluorfen is applied to weeds in Christmas tree plantations in a semi-directed manner to reduce tree contact and that only the lower branches typically receive overspray. Therefore, the risk estimates for Christmas tree shearing are probably conservative.

In addition, there were some uncertainties associated with the dietary exposure assessment. These uncertainties included the use of ½ LOQs instead of ½ LODs for field trial residue values. This would tend to overestimate the residue values from the field trial studies (all of the field trial studies were non-detects). Also, no processing or cooking studies were used in the assessment, and tolerance level residues for bananas and cacao beans and 100% crop treated for cacao beans were used. Furthermore, modeling data used to assess the concentrations of oxyfluorfen in drinking water are likely overestimates. Additional water monitoring data would enhance the drinking water estimations.

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

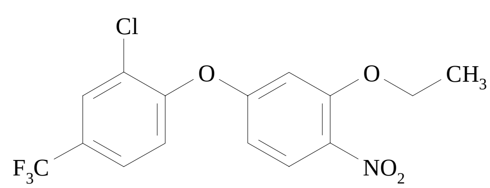
2.1 Chemical Structure and Identification

Oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] is a pre- and postemergence diphenyl ether herbicide registered for use on a variety of field crops, vegetables, and fruit trees.

According to a search of the Reference Files System (REFS) conducted 5/01/02, there are two registered manufacturing-use products (MPs) under PC Code 111601, the Dow Agrosciences 99% technical (T; EPA Reg. No. 62719-399) and the Agan Chemical Manufacturing, Ltd. 97.4% T (EPA Reg. No. 11603-29). HED notes that the Dow Agrosciences (formerly Rohm and Haas) technical registration was amended November 1999 to increase the oxyfluorfen content from 70% to 99%. Only the Dow Agrosciences and the Agan T/TGAIs are subject to a reregistration eligibility decision.

Product chemistry reviews and confidential statements of formula were reviewed in order to compare impurities in the new oxyfluorfen registrations (approximately 97% purity) with those of the earlier registration (approximately 72%). It was concluded that the new oxyfluorfen registrations (approximately 97% purity) had similar profiles of impurities, but in reduced concentrations when compared to those found in the earlier registration.

The chemical structure is shown below:



Empirical Formula:	$C_{15}H_{11}ClF_3NO_4$
Molecular Weight:	361.72
CAS Registry No.:	42874-03-3
PC Code:	111601

2.2 Physical Properties of Oxyfluorfen

Oxyfluorfen is an orange to deep red brown crystalline solid with a melting point of 65-84 °C, density of 1.49 g/mL, octanol/water partition coefficient of >20, and low vapor pressure of 2 x 10-7 torr at 20° C. Oxyfluorfen in the environment is expected to be very persistent with low mobility. Oxyfluorfen is practically insoluble in water (0.1 ppm), but is readily soluble in most organic solvents.

3.0 HAZARD CHARACTERIZATION

3.1 Hazard Profile

The toxicology database for oxyfluorfen is nearly complete. The only data gaps are for dermal and inhalation toxicity studies. As previously stated, oxyfluorfen is a diphenyl ether herbicide structurally related to lactofen and acifluorfen. The diphenyl ether herbicides act by inhibiting protoporphyrinogen oxidase, which is the second-to-last enzyme in chlorophyll biosynthesis. This enzyme is the second-to-last enzyme in heme synthesis, as well (Birchfield and Casida, *Pesticide Biochemistry and Physiology*, 1997).

The older toxicity studies with oxyfluorfen used technical material of approximately 71% or 85% purity. The newer toxicity studies used a technical material of approximately 98% purity, which is the basis for the current registrations of oxyfluorfen. The newer technical material has similar impurities to the older technical material, but in reduced concentrations.

New studies with the current 98% product that were submitted include: subchronic toxicity in rats, developmental toxicity in rats and rabbits, a battery of mutagenicity studies, and a battery of acute studies. Toxicity was less severe for studies with the 98% product than for the 71% product.

When there were studies with both the new and old technical material, consideration to an endpoint for risk assessment purposes was given to the newer, 98% technical material which is the basis of the current registrations. The studies described in this document had doses adjusted for per cent a.i. and/or for analytical concentrations determined in the diet.

Oxyfluorfen is of low acute toxicity and is in toxicity category IV for acute oral and inhalation toxicity and is category III for acute dermal toxicity. Oxyfluorfen is a slight eye and dermal irritant and is not a dermal sensitizer. Acute toxicity data for oxyfluorfen technical is summarized in Table 1.

Table 1. Acute Toxicity of Technical Oxyfluorfen

Guideline No.	Study Type	MRID	Test Material	Registrant	Results	Toxicity Category
81-1	Acute Oral	44712010	96%	Agan	LD_{50} > 5000 mg/kg	IV
		44828903	97.1%	Rohm & Haas	LD_{50} > 5000 mg/kg	IV
81-2	Acute Dermal	44712011	96%	Agan	LD_{50} > 2000 mg/kg	III
		44828904	97.1%	Rohm & Haas	LD_{50} > 5000 mg/kg	IV
81-3	Acute Inhalation	44712012	96%	Agan	LC_{50} > 3.71 mg/L	IV
81-4	Primary Eye Irritation	44712013	96%	Agan	slight irritant	IV
		44828906	96%	Rohm & Haas	negative	IV
81-5	Primary Skin Irritation	44712014	96%	Agan	slight irritant	IV
		44828905	96%	Rohm & Haas	negative	IV
81-6	Dermal Sensitization	44712015	96%	Agan	Negative	---
		44814901	23%	Rohm & Haas	Negative	
81-8	Acute Neurotox	—	—	---	—	NA

The database was adequate for subchronic feeding studies in rats and mice. A subchronic non-rodent study was not available, however, an acceptable chronic feeding study in dogs was available. The subchronic dermal and inhalation toxicity studies were classified unacceptable and are data gaps. Subchronic oral toxicity in rats was well characterized in the 1997 feeding study which used the current 98% technical material. Toxicity in this study included decreased body weights, increased urine production and water consumption, slight anemia, minor changes in other hematological parameters and clinical chemistries, slight increases in liver and kidney weights, and minor histopathological observations. Toxicity in the two 1982 feeding studies in rats with the older, 72% technical material was similar, but occurred at lower doses. Similar toxicity occurred in the 1982 mouse feeding study with the 72% technical, but also included mortality, clinical signs, and more severe liver toxicity.

The data base for chronic toxicity is considered complete and no additional chronic studies are required at this time. The 2-year combined chronic toxicity/carcinogenicity study in rats was classified unacceptable because no treatment-related toxicity occurred and because there were a number of deficiencies in this 1977 study which would not meet current guideline requirements. A new chronic toxicity study in rats was not required by the HIARC because a NOAEL could be established and because toxicity occurred in the chronic dog study at a lower dose.

Toxicity in the chronic dog study included anemia, elevated serum alkaline phosphatase enzyme, increased liver weight, lacrimation, and decreased food consumption and thin appearance. No toxicity occurred in the 2-year rat study. In the mouse carcinogenicity study, liver toxicity, shown by increased liver weights, elevated serum enzyme levels, microscopic liver lesions, and liver tumors occurred

There are acceptable developmental studies in rats and in rabbits with the current 98% technical material (1997) as well as an acceptable study in rats with 71% technical (1991) and a rabbit study with a 26.9% formulation (1981). Both maternal and developmental toxicity occurred at lower doses with the 71% technical material than with the 98% technical material. In the developmental rat study with 98% technical material, no developmental or maternal toxicity occurred. In the developmental rat study with 71% technical material, maternal toxicity included mortality, clinical signs (red vaginal discharge, soft/scant feces, thin build), and elevated liver enzymes; developmental toxicity included increased early resorptions, decreased fetal weight, and visceral and skeletal variations and malformations. In the developmental rabbit study with 98% technical material, maternal toxicity included abortions and decreased food consumption; developmental toxicity included increased late resorptions and decreased number of live fetuses per doe. In the developmental rabbit study with 26.9% formulation, maternal toxicity included mortality, abortions, clinical signs (anorexia and blood in the urine); developmental toxicity included increased early resorptions and decreased litter size.

There is an acceptable reproductive study with 71% technical material. The data base for reproductive toxicity is complete and no additional studies are required at this time. Parental toxicity included mortality, body weight decrements, and microscopic liver and kidney lesions. The kidney lesion was microscopic mineralization, which was not observed in other rat feeding studies. Offspring effects included smaller litter size and body weight decrements on day 0 of lactation.

Based upon the developmental and reproductive toxicity studies reviewed, there does not appear to be any increased susceptibility in animals due to pre- or postnatal exposure to oxyfluorfen.

The data base for carcinogenicity is considered complete. No additional studies are required at this time. The 2-year combined chronic toxicity/carcinogenicity study in rats was classified unacceptable because no treatment-related toxicity occurred and because there were a number of deficiencies in this 1977 study which would not meet current guideline requirements. A new carcinogenicity study in rats was not requested because a new study would not add to the understanding of the carcinogenic potential of oxyfluorfen. Neoplasia did not occur in this rat study but did occur at lower doses in the mouse study. In the mouse study, combined hepatocellular adenomas and carcinomas were increased in males at the high dose (8/52 vs 1/47 and 0/47 in the 2 control groups). This study was used to determine the Q_1^* for oxyfluorfen. Other diphenyl ethers are also oncongenic in rodents, and include acifluorfen, lactofen, nitrofen, and fomesafen. Nitrofen produced hepatocellular carcinomas in mice and pancreatic carcinomas in rats and acifluorfen produced a statistically significant increase in the incidence of liver tumors (adenomas and carcinomas) and stomach tumors (papillomas) in mice. Tumors were not increased in acifluorfen treated rats. Fomesafen produced hepatocellular adenomas and carcinomas in mice, and lactofen produces liver adenomas and carcinomas in mice and liver neoplastic nodules and foci of cellular alteration (possible precursor of tumors) in rats.

Based on the mouse carcinogenicity study, and in accordance with the 1986 guidance for carcinogenic risk assessment, the Cancer Peer Review Committee classified oxyfluorfen as a category C, possible human carcinogen based upon combined hepatocellular adenomas/carcinomas seen in this study. The Cancer Peer Review Committee recommended a linear, low dose extrapolation for human risk assessments with a Q_1^* of 7.32×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

The acceptable mutagenicity studies performed with the $\geq$96% test material satisfy the 1991 mutagenicity guidelines and no further testing is warranted. Table II in Appendix A shows results for 20 genetic toxicology studies performed with $\geq$96% test material, approximately 72% test material, or a polar fraction. The newer technical material (96-99% a.i.) was tested in 12 genetic toxicology studies. All assays were negative, except for one Ames assay which was positive only at high, insoluble levels. A subsequent Ames assay with 96% material was negative. The older 72% technical material and a polar fraction were tested in eight genetic toxicology studies. Both Ames assays and a mouse lymphoma study were positive for the 72% technical material. The polar fraction of the 72% technical material was also positive in an Ames assay.

Neurotoxicity is not a major component of toxicity for this chemical. Clinical signs in a developmental rat study and decreased motor activity in a rabbit developmental toxicity study were judged to be agonal in nature. No neurotoxicity studies were available for oxyfluorfen, and toxicology data did not indicate a need for requiring a neurotoxicity study.
A developmental neurotoxicity study was not required As noted above, clinical signs attributed to neurotoxicity were not observed. Additionally there were no gross or microscopic neurotoxic lesions of treatment-related damage to the nervous system and no increase in susceptibility of fetuses or offspring occurred in developmental or reproductive studies.

Two metabolism studies in rats were available and the data base for metabolism is considered complete. No additional studies are required at this time. Oxyfluorfen was rapidly absorbed, extensively metabolized, and rapidly eliminated. Most compound was eliminated in the feces; females eliminated more in the urine than did males. Bioaccumulation did not occur.

A dermal absorption factor of 18% was selected. It was determined from a dermal absorption study in rats. The 18% factor is a 10-hour value and includes compound on the skin, which is considered to be potentially absorbable.

The toxicology profile for oxyfluorfen is presented in Table 1 of Appendix A.

3.2 FQPA Considerations

The FQPA Safety Factor Committee evaluated the available hazard and exposure data for oxyfluorfen on April 9, 2001 and recommended that the FQPA safety factor to be used in human health risk assessments (as required by Food Quality Protection Act of August 3, 1996) be reduced to1x for the following reasons: (i) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; (ii) a developmental neurotoxicity study (DNT) with oxyfluorfen is **not** required; and (iii) the dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children.

3.3 Dose Response Assessment

The strengths and weaknesses of the oxyfluorfen toxicology database were considered during the process of toxicity endpoint and dose selection. The toxicology database for oxyfluorfen is adequate for selecting toxicity endpoints for risk assessment. With the availability of the requested data, the toxicity endpoints may be better defined. The only data gaps are for dermal and inhalation toxicity studies. There was reasonable confidence in the toxicity endpoints and doses for risk assessment which were selected by the Hazard Identification Assessment Review Committee (HIARC document of 4/23/2001). As stated previously, when there were studies with both the new and old technical material, consideration to an endpoint for risk assessment purposes was given to the newer, 98% technical material which is the basis of the current registrations. All doses for risk assessment purposes were assessed uncertainty factors of 10X for interspecies extrapolation and 10X and intraspecies variability. An additional uncertainty factor of 3x was applied to intermediate-term dermal, inhalation, and incidental-oral exposures because the dose was derived from a LOAEL rather than a NOAEL. An oral endpoint was selected for both the dermal and inhalation exposure. A dermal absorption factor of 18% of oral exposure was selected from the dermal absorption study in rats because the subchronic dermal toxicity study was classified as unacceptable. Inhalation exposure assessments will use an absorption factor of 100% of oral exposure.

These endpoints and doses are summarized in Table 2. An acute dietary exposure endpoint was not identified because appropriate toxicity attributed to a single exposure was not identified. The HIARC considered a 1997 developmental toxicity study in rabbits (MRID 44933102) using the 98% technical oxyfluorfen which is currently registered. The developmental NOAEL in this study was based on increased late resorptions and resulting decreased number of live fetuses/doe in the high-dose group. This endpoint was not considered appropriate for use in risk assessment because the late resorptions were primarily due to late resorptions in one doe and were not statistically significant. The 1981 developmental toxicity study in rabbits (MRID 00094052) was not considered suitable as an endpoint because it used a 26.9% wettable powder formulation from the 71% a.i. technical material which is no longer manufactured.

Since the time of endpoint selection, exposure durations have been changed from 1-7 days for short-term exposure, 7 days to several months for intermediate-term exposure, and several months to lifetime for long-term dermal or inhalation exposure. The new exposure durations are defined as 1 day to 1 month for short-term exposure, 1-6 months for intermediate-term exposure, and longer than 6 months for long-term exposure. The endpoints which were previously selected are of the appropriate duration for the new exposure durations (Memo: Changes in the definition of exposure durations for occupational/residential risk assessments performed in the Health Effects Division, June 4, 2001, HED).

A short-term incidental oral endpoint was not selected because toxicity occurring by this route and duration of exposure applicable to children was not identified. Maternal effects seen in the developmental rabbit study were not used because decreased food consumption was not accompanied by decreased body weight and clinical signs in this study were believed to be pregnancy related, and thus not related to the population of concern (infants and children). The 90-day mouse study selected for the intermediate-term incidental oral exposure, was also not used because hepatic toxicity in this study is not believed to occur after 1-7 days exposure and exposure by this short-term incidental exposure is not expected to exceed one week in duration for oxyfluorfen.

3.4 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, oxyfluorfen may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Table 2. Summary of Toxicological Dose and Endpoints for Oxyfluorfen for Use in Human Risk Assessment[1]

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	An appropriate endpoint attributed to a single dose was not identified. Therefore, an acute RfD was not established.		
Chronic Dietary	NOAEL = 3.0 UF = 100	Liver toxicity occurring in dogs and mice at the LOAEL of 200 ppm in male (33.0 mg/kg/day) and female (42.0 mg/kg/day) mice.	Chronic dog study and mouse carcinogenicity
		Chronic RfD = 0.03 mg/kg/day	
Cancer	$Q_1^* = 7.32 \times 10^{-2}$ $(mg/kg/day)^{-1}$	Combined hepatocellular adenomas and carcinomas.	Mouse carcinogenicity study
Incidental Oral, Short-Term	An appropriate endpoint attributed to short-term, incidental oral exposure was not available. Maternal effects in the developmental rabbit study were not used because decreased food consumption was not accompanied by decreased body weight and clinical signs in this study were believed to be pregnancy related, and thus not related to the population of concern (infants and children). The 90-day mouse study selected for the intermediate-term incidental oral exposure (see below), was not used because hepatic toxicity in this study is not believed to occur after 1-7 days exposure and exposure by this short-term incidental exposure is not expected to exceed one week in duration for oxyfluorfen.		
Incidental Oral, Intermediate-Term	LOAEL = 32 UF = 300	Liver toxicity and anemia seen at the LOAEL of 32 mg/kg/day.	90-day mouse[C]
Dermal, Short-Term[a]	NOAEL= 30 UF = 100	Abortions and clinical signs seen at the maternal LOAEL of 90 mg/kg/day	Developmental rabbit study (1998)
Dermal, Intermediate-Term[a]	LOAEL = 32 UF = 300	Liver toxicity and anemia seen at the LOAEL of 32 mg/kg/day.	90-day mouse
Dermal, Long-Term[a]	NOAEL = 3.0 UF = 100	Liver toxicity occurring in dogs and mice seen at the LOAEL of 18 mg/kg/day in dogs and 33 in mice .	Chronic dog study and mouse carcinogenicity
Inhalation, Short-Term[b]	NOAEL = 30 UF = 100	Abortions and clinical signs seen at the maternal LOAEL of 90 mg/kg/day.	Developmental rabbit study (1998)
Inhalation, Intermediate-Term[b]	LOAEL = 32 UF = 300	Liver toxicity and anemia seen at the LOAEL of 32 mg/kg/day.	90-day mouse
Inhalation, Long-Term[b]	NOAEL = 3.0 UF = 100	Liver toxicity occurring in dogs and mice seen at the LOAEL of 18 mg/kg/day in dogs and 33 in mice.	Chronic dog study and mouse carcinogenicity

1 This table is from the HIARC report for oxyfluorfen, dated 4/23/01.
a. An oral endpoint was used for dermal exposure: dermal absorption factor of 18% of oral exposure shall be used.
b. An oral endpoint was used for inhalation exposure: inhalation exposure assumed equivalent to oral exposure.
c. The 90-day toxicity study in rats (98% a.i.) was considered for use as an endpoint. However, this study was not selected because mice were more sensitive to the old technical (71% a.i.) than rats and no subchronic mouse study with the 98% a.i. is available.
NOAEL = no observed adverse effect level; LOAEL = lowest observed adverse effect level

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene] is a broad spectrum pre- and postemergence herbicide registered for use on a variety of field crops, vegetables, and fruit trees and is used to control certain broadleaf and grassy weeds. Agricultural uses include control of weeds in field/row crops, orchard floors, vineyard floors, and container and field grown ornamentals. In the residential environment, it is used to kill weeds on paved surfaces such as driveways, patios and sidewalks. Oxyfluorfen is sold in the United States by its basic producer, Dow Agrosciences, under the trade name Goal®.

The domestic usage of oxyfluorfen is estimated to be approximately 784,000 pounds active ingredient (ai) on 1.3 million acres. Major uses include grapes, almonds, cotton, bulb vegetables, artichokes and pasture/rangeland. There are currently 5 active emulsifiable liquid products for agricultural use and 3 granular products for commercial nursery use. There are 3 residential products which contain 0.25% to 0.70% oxyfluorfen by weight and are packaged in a Ready to Use (RTU) trigger sprayer, RTU sprinkler jug or as a liquid to be applied in a sprinkler can or hand carried tank sprayer. The application rates for the oxyfluorfen products range from 0.25 to 2.0 lbs ai per acre per application and one or two applications are typically made in the growing season. Liquid formulations are applied using groundboom, right of way and backpack sprayers. Aerial application is used only for fallow fields and chemigation is used primarily for bulb vegetables. Granular oxyfluorfen is applied to ornamentals with broadcast spreaders.

Several of the oxyfluorfen products also contain other registered active ingredient herbicides such as glyphosate - isopropylamine salt, imazapyr - isopropylamine salt; pendimethalin, oxadiazon and oryzalin. These ingredients are not addressed in this risk assessment.

A REFS search, conducted 5/2/01, identified three oxyfluorfen end-use products (EPs) registered to Dow Agrosciences. These EPs are listed below.

Oxyfluorfen EPs with Food/Feed Uses Registered to Dow Agrosciences

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
62719-395 [3]	2/22/93	2 lb/gal EC	Goal® 2E Herbicide
62719-400 [1]	11/22/95	1.6 lb/gal EC	Goal® 1.6E Herbicide
62719-424 [2]	11/18/99	2 lb/gal EC	Goal® 2XL Herbicide

[1] Including SLN Nos.AR94000600, AZ83001300, AZ93001900, AZ95000800, CA83006000, CA83006500, CA83008900, CA85005100, CA88003400, CA89000900, CA89001200, CA92000400, CA92001800, CA92002900, CA93001400, CA95000700, CA95000800, GA89000600, HI84000600, HI87000300, HI90000500, ID86001500, IN84000300, LA88000600, LA93001100, MI84000300, MI84001100, MI89000800, MI89000900, MN94000100, MS94000100, MT93000400, NC83002300, NC85000400, NC88000400, NC91000300, ND93000200, NV93000200, OR85002100, OR90001600, OR91002600, OR96000500, OR96000600, PA96000100, SC88000400, SC91000200, SC94000200, SD94000100, SD94000300, TX96000400, VA93001000, WA85002300, WA91001200, WA96000500, WI84000200, WI88000200, WI88000300, WI95000100.

[2] Including SLN Nos.AR96000900, AZ00000100, AZ96001100, AZ96001200, CA96001900, CA96002000, CA96002100, CA96002200, CA96002300, CA96002600, CA96002800, CA97001400, CA97002600, HI96001000, HI99000200, IN96000400, LA96001200, MI97000200, MN96000600, MS00001000, MS96001500, MT96000300, NC96000500, NC96000600, NC99000700, ND96000500, ND98000100, NV99000700, OR00000100, OR00002800, OR96003600, OR96003700, OR97000800, OR99000600, OR99003600, PA96000500, SC00000200, SC96000800, SC97000100, SD01000200, SD96000600, SD96000700, WA96003300, WA96003400, WA97001300, WA97002300, WA97002400, WA99003500, WI96000900, WY98000100.

[3] Including SLN Nos. AZ83001200, CA82005200, CA83005900, IA81001100, IN81001800, IN82000800, MI81002200, MI83000400, NC81002100, NC83000800, NE81001700.

4.2 Dietary Exposure/Risk Pathway

Potential dietary exposure to oxyfluorfen in the diet occurs through food and water. Data supporting food exposure are adequate and are summarized in the Residue and Product Chemistry Chapters (Attachment 2). Exposure to oxyfluorfen residues in ground and surface water was estimated using conservative modeling techniques; available monitoring data were evaluated but were considered inadequate for quantitative risk assessment purposes.

4.2.1 Dietary Exposure - Food

Tolerances for residues of oxyfluorfen in/on plant and livestock commodities [40 CFR §180.381] were previously expressed in terms of the combined residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage. The tolerance expression, however, was amended (60 FR 62330, 12/6/95) to delete the metabolites containing the diphenyl ether linkage; and is now expressed in terms of oxyfluorfen *per se*. The Agency has determined that it is no longer necessary to regulate the oxyfluorfen metabolites containing the diphenyl ether linkage because these compounds were not identified in plants, and oxyfluorfen *per se* was the major residue found in meat, meat byproducts, fat, milk, and eggs. All livestock commodity tolerances are established at 0.05 ppm, while plant commodity tolerances range from 0.05 ppm to 0.1 ppm. An adequate method is available for the enforcement of tolerances as currently defined.

The qualitative nature of the residue in plants is adequately understood. The qualitative nature of the residue in plants is based on acceptable metabolism studies conducted on tomatoes (a fruiting vegetable), onions (a bulb vegetable), and peaches (a stone fruit). The terminal residue of concern is the parent, oxyfluorfen *per se*. The qualitative nature of the residue in livestock is adequately understood based on acceptable ruminant and poultry metabolism studies. These studies indicate that the parent compound, oxyfluorfen, is also the compound of toxicological concern in milk, eggs, and livestock tissues. The Pesticide Analytical Manual (PAM) Vol. II lists two GLC/electron capture detector (ECD) methods, designated as Methods I and II, for the enforcement of tolerances for oxyfluorfen residues in/on plant and livestock commodities, respectively. Both methods determine levels of oxyfluorfen and its reduced metabolites by a common moiety (as heptafluorobutyryl derivatives of oxyfluorfen). Because oxyfluorfen *per se* is now the residue of concern, the PAM Vol. II methods are no longer suitable for enforcement purposes. The 10/99 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that oxyfluorfen *per se* is completely recovered (>80%) using Multiresidue Method Sections 302 (Luke Method; Protocol D), 303 (Mills, Onley, Gaither; Protocol E - nonfatty foods), and 304 (Mills; Protocol E - fatty foods). HED recommends that FDA's Multiresidue Methods for oxyfluorfen *per se* be utilized as the primary enforcement method for plant commodities until an enforcement method for plants to determine oxyfluorfen *per se* is validated. A single analyte enforcement method has already been proposed by the registrant (GC/ECD method designated as Method TR-34-95-111). An enforcement method for the determination of oxyfluorfen *per se* in livestock commodities is required as FDA's Multiresidue Methods are not suitable for livestock commodities.

Adequate storage stability data are also available to validate the storage intervals and conditions of various samples collected from studies pertaining to magnitude of the residue in/on plants and livestock. These storage stability data have been taken into consideration during the reassessment of established tolerances. No additional storage stability data are required for purposes of reregistration.

The reregistration requirements for data depicting magnitude of the residue in/on plants are fulfilled for the following raw agricultural commodities (RACs): artichokes; avocados; blackberries; broccoli; cabbage; cauliflower; chickpea (garbanzo beans); coffee; corn, field, fodder; corn, field, forage; corn, field, grain; cottonseed; dates; feijoa; figs; garlic; grapes; guavas; horseradish; kiwi fruits; mint, tops; olives; onions, dry bulb; papayas; pome fruits; persimmons; pistachios; pomegranates; raspberries; soybean seed; stone fruits; strawberries; taro corm; taro foliage; and tree nuts. The available field trial data for these RACs have been reevaluated for purposes of tolerance reassessment. See Table 1 of the Appendix E for tolerance reassessment information for oxyfluorfen. Overall, acceptable field trials reflecting the maximum registered use patterns and conditions under which the pesticide could be applied were conducted. The geographic representation for each commodity is generally adequate, and a sufficient number of trials reflecting the representative EC formulation class was conducted.

Additional data and/or label revisions are required for several commodities. Refer to the Product and Residue Chemistry Chapter for details of the required label amendments and/or field residue data for these RACs.

The majority of oxyfluorfen tolerances for plant commodities are established at 0.05 ppm. Most residue data indicate that residues of oxyfluorfen *per se* in/on many crop commodities are <0.01 ppm (nondetectable) and suggest that tolerances could be lowered. However, because of the possibility of an occasional residue of oxyfluorfen >0.01 ppm, and the registrant's intention to propose a new single analyte enforcement method for oxyfluorfen with a quantitation limit of 0.02 ppm, HED recommends for maintaining the existing tolerances at 0.05 ppm. HED may reassess tolerances again pending the outcome of the requested Agency petition method validation for Method TR-34-95-111.

No Codex MRLs have been established for oxyfluorfen; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

Oxyfluorfen chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model (DEEM™) software Version 7.73, which incorporates consumption data from USDA's Continuing Surveys of Food Intake by Individuals (CSFII), 1989-1992. The 1989-92 data are based on the reported consumption of more than 10,000 individuals over three consecutive days, and therefore represent more than 30,000 unique "person days" of data. Foods "as consumed" (e.g., apple pie) are linked to raw agricultural commodities and their food forms (e.g., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM software. Consumption data are averaged for the entire US population and within population subgroups for chronic exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

Anticipated residues were calculated using either USDA Pesticide Data Program (PDP) monitoring data or field trial data. Both data sets are consistent in that they show essentially all non-detectable residues, with the same limit of detection (0.01 ppm). In addition, estimates of percent crop treated (% CT) generated by EPA's Biologic and Economic Analysis Division (BEAD) were used to refine the assessment (J. Alsadek, 6/4/01 and 7/9/01).

Monitoring data for oxyfluorfen generated through the USDA PDP were from the years 1996 to 1999 (total of 3,720 samples analyzed). These data were used for the following crops: apple juice, apples, carrots, grapes, green beans (canned and fresh), high fructose corn syrup, oranges, peaches, spinach (fresh and canned), sweet corn, sweet peas, tomatoes (fresh and canned), sweet potatoes, orange juice, pears, winter squash (fresh and canned), cantaloupe, grape juice, strawberries (fresh and frozen) and sweet bell peppers. There were no residues detected on these commodities.

Although a Tier 2/3 dietary risk assessment was conducted and is the most refined assessment to date for oxyfluorfen, there are some uncertainties associated with the exposure estimates as follows: (i) the use of ½ LOQs instead of ½ LODs for field trial residue values will tend to overestimate the residue values from the field trial studies (all of the field trial studies were non-detects; therefore, this assessment is an upper bound and the real residues are somewhere between this estimate and zero); (ii) no cooking studies were used; (iii) use of tolerance level residues for bananas and cacao beans and 100% crop treated for cacao beans; and (iv) DEEM default processing factors were used in the assessment.

4.2.2 Acute Dietary

No adverse effects reflecting a single dose was identified; therefore, no acute endpoint was selected. An acute dietary risk assessment was not conducted.

4.2.3 Chronic Dietary

The chronic risk assessment conducted using anticipated residues and % CT provided by the Biological and Economics Analysis Branch and calculated using a chronic PAD of 0.03 mg/kg/day are significantly below HED's level of concern (<1% cPAD) for all population subgroups assessed (Table 4).

Table 4. Chronic Dietary Exposure Summary for Oxyfluorfen

Population	Exposure (mg/kg body wt/day)	%cPAD
U.S. Population	0.000005	<1
All Infants	0.000011	<1
Children (1-6 yrs old)	0.000012	<1
Children (7-12 yrs old)	0.000009	<1
Females (13-50 yrs old)	0.000004	<1
Males (13-19 yrs old)	0.000005	<1
Males (20+ yrs)	0.000004	<1
Seniors (55+ yrs)	0.000004	<1

4.2.4 Cancer Dietary

Oxyfluorfen is classified as a category C, possible human carcinogen based upon combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. The Cancer Peer Review Committee recommended a linear, low dose extrapolation for human risk assessments, with a Q_1* of 7.32 x 10^{-2} $(mg/kg/day)^{-1}$ human equivalents. Using the Q_1* of 7.32 x 10^{-2} results in a maximum estimated lifetime cancer risk to the U.S. general population of 3.8 x 10^{-7} . Risks estimates above 1 x 10^{-6} are considered to be of concern; therefore, based on this analysis, HED does not consider the cancer risk to be of concern.

4.3 Water Exposure/Risk Pathway

The Environmental Fate and Effects Division provided the drinking water assessment using simulation models to estimate the potential concentration of oxyfluorfen in ground and surface water. Limited water monitoring data are available for oxyfluorfen but these data are not adequate to perform a quantitative drinking water assessment. Oxyfluorfen in the environment is expected to be very persistent with low mobility. In general oxyfluorfen degrades very slowly in both soil and water and binds strongly to soil containing organic matter. Oxyfluorfen’s capacity to bind strongly to soil reduces its potential to contaminate ground water. However, the chemical’s persistence suggests that if contamination did occur, the material would be stable in the ground water. Modeling results generally predict low concentrations in surface and groundwater. However, when oxyfluorfen reaches water it is likely to persist for long periods.

Surface Water Modeling PRZM 3.12/ EXAMS 2.7.97 modeling was performed with index reservoir (IR) scenarios and percent cropped area (PCA) adjustment factors. Three different crop scenarios; citrus in Florida, apples in Oregon, and cotton in Mississippi were chosen to estimate the concentration of oxyfluorfen in surface drinking water. These scenarios were chosen to represent a geographically dispersed range of modeled surface water concentrations in areas representative of where oxyfluorfen is heavily used (west coast states and the Mississippi delta region) or has the potential for heavy use (Florida). A default percent crop area (PCA) adjustment factors were applied. Although the modeling results for citrus produce higher results, EFED believes the limitation of oxyfluorfen use to non-bearing citrus precludes large portions of watersheds from being treated simultaneously, as is simulated in the model and it is unlikely that a substantial portion of a watershed would be comprised of non-bearing citrus. The term “non-bearing” refers to young trees which are not producing substantial quantities of fruit and is distinct from dormant trees which are not in a fruiting season. Accordingly, EFED recommended the apple scenario be used for the drinking water concentration of oxyfluorfen in surface water since it provides a more realistic screening-level drinking water concentration.

TABLE 4. TIER 2 CONCENTRATION OF OXYFLUORFEN IN SURFACE WATER USING IR/PCA PRZM/EXAMS SCENARIOS						
Crop Scenario	**Application Rate** (lbs ai/acre)	**Number of Applications**	**PCA Adjustment Factor**	**1/10 Peak Conc.**	**1/10 Yearly Conc.**	**36 Year Annual Mean Conc.**
Citrus (non-bearing)	2.0 lbs ai/acre	2	0.87 (default)	51.6 µg /L	10.4 µg /L	7.4 µg /L
Apples*	2.0 lbs ai/acre	1	0.87 (default)	23.4 µg /L	7.1 µg /L	5.7 µg /L
Cotton	0.5 lbs ai/acre	1	0.87 (default)	13.6 µg /L	5.1 µg /L	3.2 µg /L
Cotton	0.5 lbs ai/acre	1	0.20 (cotton)	3.1 µg /L	1.2 µg /L	0.7 µg /L

***** Used by HED as screening-level drinking water concentrations as recommended by EFED.

Ground Water Modeling: SCI-GROW modeling was used to estimate the concentration of oxyfluorfen in drinking water from shallow ground water sources. The model estimates upper-bound ground water concentrations of pesticides likely to occur when the pesticide is used at the maximum allowable rate in areas where ground water is vulnerable to contamination. Since SCI-GROW, unlike the PRZM/EXAMS surface water models, does not require a specific crop scenario, EFED used the highest use rate of four applications at 2.0 lbs ai/acre as used for ornamentals to estimate the concentration of oxyfluorfen in drinking water from shallow groundwater sources.

The SCI-GROW model estimated the concentration of oxyfluorfen in drinking water from shallow ground water sources to be **0.08** µg/L. This concentration can be considered as both the acute and chronic value.

Monitoring data. There are limited surface water monitoring data available for oxyfluorfen. It was not analyzed as a standard analyte under the National Water-Quality Assessment (NAWQA) Program of the U.S. Geological Survey (USGS). The USGS did, however, measure oxyfluorfen concentrations in suspended sediment in the San Joaquin River in central California. The data showed frequent detections of oxyfluorfen associated with sediment during several years in the 1990's. Average concentrations of oxyfluorfen associated with suspended sediment at four sites ranged from **1.0** to **27.2 ppb** (Bergamaschi et al 1997). In addition to the USGS data, some samples have been collected and analyzed for oxyfluorfen in water and sediments in the Columbia River basin of Oregon and Washington. These data were collected as a result of an oxyfluorfen spill into the creek yards from where the creek enters the Columbia River. Oxyfluorfen measurements were made in water, soil, and sediment in response to the spill and several samples were taken in areas that were unaffected by the spill. Most samples collected up and downstream outside the spill site contained undetectable levels (< 0.01 ppb) of oxyfluorfen. Excluding the two weeks immediately following the spill, only 7 of approximately 300 water samples collected in the Columbia contained any detectable levels of oxyfluorfen. The detections were at relatively high levels and were most likely a result of leakage from the spill site. The few water samples collected from nearby rivers contained undetectable levels. Of 35 background sediment measurements made in nearby rivers and streams which were unaffected by the spill, 2 detections of oxyfluorfen in sediment were noted. The highest detection, 541 ppb in Mosier Creek, is downstream of orchards.

The data are not adequate to perform a quantitative drinking water assessment because: 1) dissolved oxyfluorfen concentrations are most relevant to drinking water concentrations but some data are limited to sediment levels; 2) oxyfluorfen use is widespread but the monitoring data are limited to a few locations; and 3) oxyfluorfen application timing is broad and guideline fate data suggest it is likely to be persistent but the monitoring data are temporally limited.

4.4 Residential Exposure/Risk Pathway

Oxyfluorfen is used in the residential environment by homeowners to kill weeds on patios, driveways and similar surfaces. Based on this use pattern, HED has determined that exposure to homeowners would result in short-term exposure. Intermediate-term and chronic exposures as a result of residential uses are not expected. The following four scenarios serve as the basis for the quantitative exposure and risk assessments:

- (1) Spot Treat Weeds Using a Low Pressure Tank Sprayer
- (2) Spot Treat Weeds Using a “Mix Your Own” Sprinkler Can
- (3) Spot Treat Weeds Using a RTU Invert Sprayer
- (4) Spot Treat Weeds Using a RTU Trigger Sprayer

In calculating the residential exposures, a series of assumptions and exposure factors were used and served as the basis for completing the residential handler risk assessments as summarized below.

- Exposure data for scenarios #1 and #4 were taken from a carbaryl mixer/loader/applicator exposure study. These data are from the Outdoor Residential Exposure Task Force (ORETF). There is no data compensation issue associated with the use of the ORETF data in the oxyfluorfen because Dow Agrosciences, the registrant for oxyfluorfen, is a member of the ORETF. Surrogate exposure data for scenarios #2 and #3 were derived from an ORETF proprietary study (OMA004) that was conducted during the application of an emulsifiable concentrate of diazinon to lawns using “Mix Your Own” and Ready to Use” hose end sprayers.
- The oxyfluorfen products are used for spot treatment only, they are not used for broadcast treatment of lawns because they kill grass.
- Clothing consisted of a short-sleeved shirt, short pants and no gloves.
- An area of 200 square feet would be treated per application using one gallon of the “ready to use” product or 2.67 quarts of the “mix your own” product in an invert jug or sprinkler can.
- An area of 300 square feet would be treated per application using one gallon of Kleenup Super Edger in a low pressure hand carried tank sprayer.
- Two applications would be made per year.
- Applicators would have 50 years of potential exposure over a 70 year lifespan.

4.4.1 Exposure and Risk Estimates for Non-Cancer Effects

The residential exposure scenarios yielded the following MOEs which exceeded the target MOE of 100 and are therefore not of concern (Table 5).

Table 5. Risk Estimates for Non-cancer Effects

Scenario No.	Scenario	Combined Absorbed Daily Dose (mg/kg/day)	MOE
1	Spot Treat Weeds Using Low Pressure Tank Sprayer	2.5×10^{-3}	12000
2	Spot Treat Weeds Using a “Mix Your Own” Sprinkler Can	1.4×10^{-3}	22000
3	Spot Treat Weeds Using a RTU Invert Sprayer	1.8×10^{-4}	170000
4	Spot Treat Weeds Using a RTU Trigger Pump Sprayer	3.5×10^{-3}	8500

a. Combined Absorbed Daily Dose (CADD) (mg/kg/day) = Dermal Absorbed Daily Dose (mg/kg/day) + Inhalation Absorbed Daily Dose (mg/kg/day)
b. MOE = NOAEL (mg/kg/day)/CADD (mg/kg/day). Where NOAEL = 30 mg/kg/day for short-term exposures.
c. A Margin of Exposure (MOE) of 100 or greater is acceptable for Oxyfluorfen.

4.4.2 Exposure and Risk Estimates for Cancer

The residential exposure scenarios yielded the cancer risks listed in Table 6 below. These risks are not of concern because they are less than 1.0×10^{-6}.

Table 6. Risk Estimates for Cancer Effects

Scenario No.	Scenario	LADD	Cancer Risk
1	Spot Treat Weeds Using Low Pressure Tank Sprayer	8.5×10^{-6}	6.2×10^{-7}
2	Spot Treat Weeds Using a “Mix Your Own” Sprinkler Can	4.6×10^{-6}	3.3×10^{-7}
3	Spot Treat Weeds Using a RTU Invert Sprayer	5.9×10^{-7}	4.3×10^{-8}
4	Spot Treat Weeds Using a RTU Trigger Sprayer	1.2×10^{-5}	8.7×10^{-7}

It should be noted that cancer risk is calculated based on an annual average exposure, and does not depend upon the amount used in any one day. Thus the cancer risk will be the same as listed above providing that no more than two gallons of the “ready to use” or 5.3 quarts of the “mix your own” product are used per year.

None of the residential applicator scenarios are of concern because the MOEs for non-cancer effects are greater than 100 and the cancer risks are less than 1.0 x 10^{-6}. It is suspected that the hose end sprayer data overestimates the exposure from the sprinkler can (scenario 2) and invert jug (scenario 3) methods because the hose end sprayer operates at a higher pressure and is more prone to leakage.

4.5 Residential Postapplication Exposure and Risks

Post application residential exposures were not quantified because residential uses are limited to spot treatments which do not include broadcast application to lawns. In addition, the label states that oxyfluorfen kills grass. Although there is the possibility that exposures could occur on a treated brick patio or other treated areas, these exposures would be minimized by the fact that the spray would be absorbed into the surface.

4.6 Other Residential Exposures

This assessment for oxyfluorfen reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines*, the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment*, and the *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment* presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). The Agency is, however, currently in the process of revising its guidance for completing these types of assessments. Modifications to this assessment shall be incorporated as updated guidance becomes available. This will include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources not addressed in this document such as from spray drift and exposures to farmworker children.

4.6.1 Spray drift

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from groundboom application methods. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from pesticide residues in food and other exposures for which there is reliable information. These other exposures include drinking water and non-occupational exposures, e.g., to pesticides used in and around the home. Risk assessments for aggregate exposure consider both short-, intermediate- and long-term (chronic) exposure scenarios considering the toxic effects which would likely be seen for each exposure duration.

Oxyfluorfen is a food use chemical. Drinking Water Levels of Comparison (DWLOC) have been calculated for oxyfluorfen. There are residential (non-occupational) uses of oxyfluorfen; therefore, the considerations for aggregate exposure are those from food, drinking water and residential exposure.

5.1 Acute Risk

An acute endpoint was not identified by the HIARC; therefore, no acute aggregate risk assessment is required.

5.2 Chronic Aggregate Risk Assessment

When drinking water concentrations are estimated using modeling as was the case for oxyfluorfen, Drinking Water Levels of Comparison are calculated (DWLOCs). DWLOCs represent the maximum contribution to the human diet, in µg/L, that may be attributed to residues of a pesticide in drinking water after dietary and residential exposure is subtracted from the cPAD. Since no chronic residential scenarios have been identified, chronic DWLOCs for oxyfluorfen were calculated based on anticipated residues in food alone. These are presented in Table 9. Comparisons are made between DWLOCs and the estimated concentrations of oxyfluorfen in surface water and ground water generated via PRZM/EXAMS and SCI-GROW, respectively. If model estimates are less than the DWLOC, there is generally no drinking water concern. DWLOC calculations used the following equation and standard body weight and water consumption values, i.e., 70 kg/2L (adult male), 60 kg/2L (adult female) and 10 kg/1L (child).

$$DWLOC_{chronic}\ (ug/L) = \frac{[\text{chronic water exposure (mg/kg bw/day)} \times \text{(body weight (kg))}]}{[\text{water consumption (L)} \times 10^{-3}\ \text{mg/µg}]}$$

where chronic water exposure (mg/kg/day) = [cPAD - (chronic food (mg/kg/day)]

Table 9. Oxyfluorfen Summary of Chronic DWLOC Calculations

Population Subgroup	cPAD (mg/kg/day)	Food Exposure (mg/kg/day)	Available Water Exposure (mg/kg/day)	DWLOC (ug/L)	Surface Water [1] (Overall mean) (ppb)	Ground Water (ug/L)
U.S. Population	0.03	0.000005	0.030	1050	7.1	0.08
Females 13-50 yrs	0.03	0.000004	0.030	900	7.1	0.08
Children 1-6 yr	0.03	0.000012	0.030	300	7.1	0.08
All Infants	0.03	0.000011	0.030	300	7.1	0.08

Oxyfluorfen surface water EECs are from PRZM-EXAMS modeling; ground water EECs are from SCI-GROW

$$\text{DWLOC} = \frac{\text{water exposure X body weight}}{\text{Liters of water X}10^{-3}}$$ where water exposure = cPAD - food exposure

Body weight = 70 kg for U.S. Population, 60 kg for females, 10 kg for infants and children
Liters of water = 2L for Adults and 1L for infants and children

Chronic DWLOCs. As shown in Table 9, comparison of the chronic DWLOCs with the environmental concentrations of oxyfluorfen estimated using conservative modeling, surface and groundwater concentrations are substantially less than the DWLOCs for all populations. Consequently, there is no chronic aggregate concern for drinking water from surface or groundwater sources.

5.3 Cancer Aggregate Risk Assessment

Cancer DWLOCs were calculated using food alone and together with residential exposure data. The handler exposure scenario which resulted in the greatest risk (scenario #4, Spot treatment of weeds using a RTU Trigger Pump Sprayer) was used in the calculation. DWLOC calculations were done for adults only using the following equation and standard body weight and water consumption, i.e., 70 kg/2L (adult male).

$$\textit{Cancer DWLOC}(\mu g/L) = \frac{[\textit{chronic water exposure (mg/kg bw/day) x body weight (kg)}]}{[\textit{water consumption (L) x } 10^{-3}\ mg/\mu g]}$$

Where: *Chronic Water Exposure (mg/kg/day) = [negligible risk/Q*] - [(chronic food exposure + residential exposure (Lifetime Average Daily Dose))]*

Table 10a. Cancer DWLOC Calculations (Food only)

Population	Q*	Negligible Risk Level	Target Max Exposure[1] mg/kg/day	Chronic Food Exposure mg/kg/day	Max Water Exposure[2] mg/kg/day	Surface Water EEC[3] (ug/L)	Ground Water[3] EEC (*ug/L*)	Cancer DWLOC[4] (µg/L)
U.S. Pop	7.32×10^{-2}	1×10^{-6}	1.4×10^{-5}	5×10^{-6}	9×10^{-6}	5.7	0.08	0.315

[1] Target Maximum Exposure (mg/kg/day) = [negligible risk/Q*]
[2] Maximum Water Exposure (mg/kg/day) = [Target Maximum Exposure - Chronic Food Exposure]
[3] The crop producing the highest level was used.
[4] $$\text{Cancer DWLOC}(\mu g/L) = \frac{[\text{maximum water exposure (mg/kg/day) x body weight (kg)}]}{[\text{water consumption (L) x } 10^{-3}\ mg/\mu g]^{2}}$$

Table 10b. Cancer DWLOC Calculations (Food and Residential)										
Population	Q*	Negligible Risk Level	Target Max Exposure[1] mg/kg/day	Chronic Food Exposure mg/kg/day	Residential Exposure (LADD) mg/kg/day	Aggregate cancer exposure (food and residential) mg/kg/day	Max Water Exposure[2] mg/kg/day	Surface Water EEC[3] (ug/L)	Ground Water[3] EEC (*ug/L*)	Cancer DWLOC[4] (µg/L)
U.S. Pop	7.32×10^{-2}	1×10^{-6}	1.4×10^{-5}	5×10^{-6}	1.2×10^{-5}	1.7 x 10-5	0	5.7	0.08	0

[1] Target Maximum Exposure (mg/kg/day) = [negligible risk/Q*]
[2] Maximum Water Exposure (mg/kg/day) = [Target Maximum Exposure - (Chronic Food Exposure + Residential Exposure (Lifetime Average Daily Dose))]
[3] The crop producing the highest level was used.
[4] Cancer DWLOC(µg/L) = $\frac{\text{[maximum water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/µg]}}$ [2]

Cancer DWLOCs. Upon comparison of the cancer DWLOCs with the environmental concentrations of oxyfluorfen estimated using conservative modeling, surface and groundwater concentrations are greater than the cancer DWLOCs when considering both food and residential uses. EECs for surface water are also greater than the DWLOC when food exposure is considered alone. Thus, there appears to be a potential for oxyfluorfen residues in drinking water to occur at levels of concern. Drinking water monitoring data would allow refinement of the estimated environmental concentrations (EECs). It should be noted that further refinement of the dietary or residential risk estimate will not result in acceptable aggregate cancer risks, since EECs will exceed cancer DWLOCs even if the entire risk cup were reserved for water. Furthermore, surface water EEC's will exceed cancer DWLOCs for other use sites (e.g. apples) as well.

5.4 Short-term Aggregate Risk Assessment

Short-term DWLOCs were calculated based upon average food residues and residential handler exposure. The handler exposure scenario which resulted in the greatest risk (scenario #4, Spot treatment of weeds using a RTU Trigger Pump Sprayer) was used in the calculation. The DWLOC calculation was done for adults only using the following equation and standard body weight and water consumption, i.e., 70 kg/2L (adult male) and 60kg/2L (adult female).

$$\text{DWLOC(µg/L)} = \frac{\text{[maximum water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/µg]}}$$

where maximum water exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)

Table 11. Short-Term Aggregate Risk and DWLOC Calculations (Inhalation/Dermal Endpoints and NOAELs the Same)	
Population	Short -Term Scenario

	NOAEL mg/kg/day	Target MOE[1]	Max Exposure[2] mg/kg/day	Average Food Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]	Max Water Exposure[5] mg/kg/day	Surface Water EEC[6] (*units*)	Ground Water EEC[6] (*units*)	Short-Term DWLOC[7] (µg/L)
Adult Male	30	100	0.3	0.000005	0.0035	8600	0.296	7.1	0.08	10400
Adult Female	30	100	0.3	0.000004	0.0035	8600	0.296	7.1	0.08	8900

[1] Short-term dermal and inhalation NOAEL = 30 from a developmental rabbit study.
[2] Maximum Exposure (mg/kg/day) = NOAEL/Target MOE
[3] Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure]
[4] Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]
[5] Maximum Water Exposure (mg/kg/day) = Target Maximum Exposure - (Food Exposure + Residential Exposure)
[6] The crop producing the highest level was used.
[7] DWLOC(µg/L) = $\frac{\text{[maximum water exposure (mg/kg/day) x body weight (kg)]}}{\text{[water consumption (L) x } 10^{-3} \text{ mg/µg]}}$

Short-term DWLOCs. As shown in Table 11, surface and ground water concentrations estimated using conservative modeling are below the short-term DWLOCs for oxyfluorfen. Consequently, there is no short-term exposure concern for drinking water from surface or groundwater sources.

6.0 CUMULATIVE RISK

The Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

HED did not perform a cumulative risk assessment as part of this reregistration for oxyfluorfen because HED has not yet initiated a review to determine if there are any other chemical substances that have a mechanism of toxicity common with that of oxyfluorfen. For purposes of this reregistration decision EPA has assumed that oxyfluorfen does not have a common mechanism of toxicity with other substances.

On this basis, the registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether oxyfluorfen shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for oxyfluorfen need to be modified or revoked. If HED identifies other substances that share a common mechanism of toxicity with oxyfluorfen, HED will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment once the final guidance HED will use for conducting cumulative risk assessments is available.

HED has recently developed a framework that it proposes to use for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued for public comment on June 30, 2000 (65 FR 40644-40650) and is available from the OPP Website at: *http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-30/6049.pdf* In the draft guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed. The proposed guidance on cumulative risk assessment of pesticide chemicals that have a common mechanism of toxicity is expected to be finalized by the summer of 2001.

Before undertaking a cumulative risk assessment, HED will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the "*Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity*" (64 FR 5795-5796, February 5, 1999).

7.0 OCCUPATIONAL EXPOSURE

Occupational exposure and risk assessment is required for an active ingredient if: (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (i.e., mixers, loaders, applicators, etc.) during use or to persons entering treated areas after application is completed. Oxyfluorfen (2-chloro-1- (3-ethoxy-4-nitrophenoxy)-4-trifluoromethylbenzene; CAS # 42874-03-3) meets both criteria. Oxyfluorfen is a diphenyl ether in acute toxicity categories IV by the oral, dermal and inhalation routes. There is potential exposure to private grower and custom applicators from agricultural site applications of oxyfluorfen.

7.1 Occupational Handlers/Applicators

HED has determined that pesticide handlers/applicators are likely to be exposed during oxyfluorfen use and that these uses would result in short (1 day to 1 month) and intermediate-term (1 to 6 months) exposures. Chronic exposures (longer than 6 months) are not expected because oxyfluorfen is only applied a few times per year. There are two populations of workers exposed to oxyfluorfen during the mixing/loading and application in the agricultural environment. These include private growers who apply oxyfluorfen only to their own farms and custom applicators who apply oxyfluorfen to multiple farms. Based upon the application methods shown in Table 12, the following exposure scenarios were developed. These scenarios serve as the basis for the quantitative occupational applicator exposure and risk assessments.

Table 12. Exposure Scenarios

Application Method	Exposure Scenario
1. Large Groundboom	1A - Mix/Load Liquids - Large Groundboom
	1B - Spray Application - Large Groundboom
2. Small Groundboom	2A - Mix/Load Liquids - Small Groundboom

Table 12. Exposure Scenarios	
Application Method	**Exposure Scenario**
	2B - Spray Application - Small Groundboom
3. ATV Groundboom	3A - Mix/Load Liquids - ATV Groundboom
	3B - Spray Application - ATV Groundboom
4. Fixed Wing Aircraft	4A - Mix/Load Liquids for Aerial Application
	4B - Spray Application - Fixed-Wing Aircraft
	4C - Flag Aerial Applications
5. Chemigation	5 - Mix/Load Liquids - Chemigation
6. Right of Way (ROW) Sprayer	6A - Mix/Load Liquids - ROW Sprayer
	6B - Spray Application - ROW Sprayer
7. Backpack Sprayer	7 - Mix/Load/Apply Liquids - Backpack
8. Tractor Drawn Broadcast Spreader	8A - Load Granules into Broadcast Spreader
	8B - Apply Granules with Broadcast Spreader
9. Push Type Broadcast Spreader	9 - Broadcast Spreader (Load/Apply)

The following assumptions and factors were used in order to complete the exposure and risk assessments for occupational handlers/applicators:

- The average work day was 8 hours.
- The daily acreages treated were taken from EPA Science Advisory Council for Exposure Policy #9 "Standard Values for Daily Acres Treated in Agriculture," Revised July 5, 2000.
- Maximum application rates and daily acreage were used to evaluate non-cancer occupational risk.
- Average application rates and daily acreage were used to evaluate cancer occupational risk.
- The supplemental label maximum application rate for right of way areas was estimated to be 2.0 pounds per acre with a minimum spray volume of 40 gallons per acre.
- A body weight of 60 kg was assumed for short-term exposures because the short-term endpoint relates to females 13-50 years of age.
- A body weight of 70 kg was assumed for intermediate-term exposures because the intermediate-term endpoint is not gender specific.
- A body weight of 70 kg was assumed for cancer scenarios.
- A private grower mixes, loads and applies liquid formulation of oxyfluorfen 5 days per year. This is based upon the 90th to 95th percentile farm size (taken from the 1997 Census of Agriculture) divided by the assumed acres treated per day. It is also assumed that approximately one or two applications are made per year as listed

in the NASS data.

- A private grower loads and applies granular formulations of oxyfluorfen 10 days per year because the granular labels allow up to 4 applications of 2 lb/ai per year.
- A custom applicator mixes, loads and applies oxyfluorfen 30 days per year.
- The dermal absorption rate is 18% based upon a dermal absorption study in rats using oxyfluorfen.
- The inhalation absorption rate is assumed to be 100% relative to oral absorption.
- Baseline PPE includes long sleeve shirts, long pants and no gloves or respirator.
- Single Layer PPE includes baseline PPE with gloves.
- Double layer PPE includes coveralls over single layer PPE.
- Double layer PPE PF5 includes above with a PF5 respirator (i.e. dust mask)
- Double layer PPE PF10 includes above with a PF10 cartridge respirator
- Only closed cockpit airplanes are used for aerial application.

7.1.1 Exposure and Risk Estimates for Non-Cancer Effects

Analyses for handler/applicator exposures were performed using the Pesticide Handlers Exposure Database (PHED) data and data from one worker exposure study (ORETF # OMA001) which was used to evaluate the exposure for scenario #9-Push type broadcast spreader (Load/apply). PHED , was designed by a task force of representatives from the US EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. It is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

The non-cancer combined MOEs indicate a wide range for the various exposure scenarios as indicated in Table 13.

Table 13. Non-Cancer Combined MOEs for Occupational Exposure to Oxyfluorfen

Endpoint	Baseline MOEs	Single Layer PPE MOEs
Short-term	5.7 - 14000	490 - 14000
Intermediate-term	7.1 - 17000	520 - 15000
Scenarios are of concern when the MOE <100 for short-term exposures or the MOE <300 for intermediate-term exposures		

A brief summary of the specific exposure scenarios which exceeded the Agency's level of concern (i.e. combined MOEs less than 100 (short -term) or 300 (intermediate-term)) is presented in Table 14. A more complete tabulation of the calculations is presented in Appendix B.

Table 14 - Oxyfluorfen Handler Exposure Scenarios of Concern[a]	
Mitigation Level	**Scenarios of Concern (MOE = Short-term, Intermediate-term)**
Baseline PPE	1A - Mix/load liquids - Large Groundboom (MOE =23 to 34, 29 to 43) 2A- Mix/load liquids - Average Groundboom (MOE = 22 to 85, 27 to 110) 3A- Mix/load liquids - ATV Groundboom (MOE = 43, 54) 4A- Mix/load liquids - Aerial (MOE = 6, 7) 5 - Mix/load liquids - Chemigation (MOE =20, 24) 6A- Mix/load liquids - Right of Way Sprayer (MOE = 69, 86) 6B - Spray Application - Right of Way (MOE = 150, 190)
Single Layer PPE (without respirators)	None
a. Scenarios are of concern when the MOE <100 for short-term exposures or the MOE <300 for intermediate-term exposures	

As shown in Table 14, the calculations of occupational handler/applicator risk indicate that, at the single layer PPE level (which includes chemical resistant gloves but does not include respiratory protection), none of the scenarios are of concern for short or intermediate-term non-cancer risks.

7.1.2 Exposure and Risk Estimates for Cancer Effects

An occupational cancer assessment was also conducted. The Agency has defined a range of acceptable cancer risks based on a policy memorandum dated August 15, 1996, by then Office of Pesticide Programs Director Dan Barolo. This memo refers to a predetermined quantified "level of concern" for occupational carcinogenic risk. Risks that are 1×10^{-6} or lower require no risk management action. For those chemicals subject to reregistration, the Agency is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protection are warranted as is commonly applied with noncancer risk estimates (e.g., additional PPE or engineering controls). Carcinogenic risks that remain above 1.0×10^{-4} at the highest level of mitigation appropriate for that scenario remain a concern.

Average daily doses for cancer risk assessments are calculated in the same manner as non-cancer risk assessment except that the average application rates and acres treated per day are used instead of the maximum rates. Once the average daily dose is calculated, a Lifetime Average Daily Dose (LADD) is calculated. To obtain the cancer risk associated with a specific exposure scenario, the LADD is multiplied by Q_1* (7.3×10^{-2}) as summarized below.

<u>Lifetime Average Daily Dose (LADD) is calculated:</u>

LADD = Combined Dose x (# days worked/365 days per year) x (35 years worked/70 year lifetime)
(mg/kg/day) (mg/kg/day)

[Note: The number of days worked is assumed to be 30 for custom applicators and 5 to 10 for private growers.]

Cancer Risk is calculated:

Cancer Risk = LADD (mg/kg/day) x Q_1^* $(mg/kg/day)^{-1}$

The overall results of cancer risk calculations for private growers and custom handlers/applicators are summarized in Table 15. Scenarios of concern where the cancer risk exceed 1.0×10^{-4} are listed in Table 16 for custom applicators and in Table 17 for private growers. A more detailed tabulation of the calculations is provided in Appendix B.

Table 15. Cancer Risks for Private Grower and Custom Handlers and Applicators

Cancer Risk	Single Layer PPE	Double Layer	Double Layer PF5	Double Layer PF10	Engineering Controls
Private grower	7.2×10^{-7} to 8.5×10^{-6}	5.7×10^{-7} to 6.7×10^{-6}	2.8×10^{-7} to 4.2×10^{-6}	2.5×10^{-7} to 4.2. x 10^{-6}	1.8×10^{-8} to 1.0×10^{-6}
Custom Applicator	3.6×10^{-6} to 8.0×10^{-5}	3.4×10^{-6} to 6.0×10^{-5}	1.6×10^{-6} to 5.7×10^{-5}	1.3×10^{-6} to 5.7×10^{-5}	1.1×10^{-7} to 1.4×10^{-5}

The cancer risks for all of the custom applicator scenarios are less than 1×10^{-4} at the single layer PPE level and some of the applicator scenarios are less that 1.0×10^{-5} . At the highest level of mitigation (engineering controls) the risks for all of the custom applicator scenarios are reduced to less than 1×10^{-5} and some are reduced to less than 1×10^{-6}.

Table 16 - Custom Handler/Applicator Cancer Risks of Concern

Mitigation Level	Scenarios That Exceed 1×10^{-4}	Scenarios That Exceed 1×10^{-5}	Scenarios That Exceed 1×10^{-6}
Single Layer PPE	None	1A,1B, 2A,2B, 4A, 5, 6A, 6B, 7, 9	All
Double Layer	None	1A, 1B, 2A, 4A, 5, 6B, 7	All
Double Layer PF5	None	1A, 2A, 4A, 5, 6B, 7	All
Double Layer PF10	None	Same as above	All
Engineering Controls	None	None	All Except 2B, 4C, 8A, 8B

Scenario Descriptions

(1) Large Groundboom: 1A - Mix/Load Liquids, 1B - Apply
(2) Average Groundboom: 2A - Mix/Load Liquids, 2B - Apply
(3) ATV Groundboom: 3A - Mix/Load Liquids, 3B - Apply
(4) Fixed Wing Aircraft: 4A - Mix/Load Liquids, 4B - Apply, 4C - Flag
(5) Chemigation: Mix/Load Liquids
(6) Right of Way Sprayer: (6A) - Mix/Load, (6B) - Apply
(7) Backpack (Mix/Load/Apply),
(8) Tractor Drawn Broadcast Spreader: 8A - Load Granules, 8B - Apply Granules
(9) Push Type Broadcast Spreader (Load/Apply)

The cancer risks for all of the private grower scenarios are less than 1.0 X 10^{-5} at the single layer PPE level. Higher levels of PPE reduce the risk to 1.0 X 10^{-6} or less for some of the scenarios and engineering controls reduce the risk to 1.0 x 10^{-6} or less for most of the scenarios.

Table 17 - Private Grower Handler/Applicator Cancer Risks of Concern		
Mitigation Level	Scenarios That Exceed 1 x 10^{-5}	Scenarios That Exceed 1 x 10^{-6}
Single Layer PPE	None	1A, 1B, 2A, 2B, 3A, 5, 7, 8A, 8B, 9
Double Layer PPE	None	1A, 1B, 2A, 2B, 3A, 5, 7, 8A, 8B, 9
Double Layer PPE	None	1A, 1B, 2A, 2B, 5, 7, 9
Double Layer PPE	None	1A, 1B, 2A, 2B, 5, 7, 9
Engineering Controls	None	1A only at the rate for corn (1.2 x 10^{-6})
Scenario Descriptions (3) ATV Groundboom: 3A - Mix/Load Liquids, 3B - Spray Application (8) Tractor Drawn Broadcast Spreader: 8A - Load Granules, 8B - Apply Granules (9) Push Type Broadcast Spreader (Load/Apply)		

7. 2 Post-Application Occupational Exposure and Risk Estimates

Post application oxyfluorfen exposures can occur in the agricultural environment when workers enter fields recently treated with oxyfluorfen to conduct tasks such as scouting, irrigation and thinning. A private grower is defined as a single grower or employee who only enters fields owned by that particular grower while a commercial worker may enter fields owned by multiple growers.

Oxyfluorfen is a non-selective herbicide that can cause leaf damage to most of the labeled crops. For this reason, the liquid product labels specify that it should be applied to the ground in such a manner as to minimize crop damage and the granular product labels specify that it should be watered in to rinse the granules off of the foliage. With the exceptions of bulb vegetables and conifers, which have more tolerance to oxyfluorfen, over the top applications are not recommended. Re-entry workers may be exposed to oxyfluorfen during a variety of agricultural scenarios listed in Table 18 for some of the crops treated with oxyfluorfen. Because oxyfluorfen is typically applied only a couple of times per season and because the agricultural scenarios occur for only a few months per year, it was determined that oxyfluorfen exposures would be in the range covered by the short and intermediate-term toxicological endpoints. Potential inhalation exposures are not anticipated for the post-application worker scenarios because of the low vapor pressure of oxyfluorfen (2 x 10^{-07} torr at 20°C), and the Agency currently has no policy/method for evaluating non-dietary ingestion by workers due to poor hygiene practices or smoking. As a result, only dermal exposures were evaluated in the post-application worker assessment.

In the Worker Protection Standard (WPS) a restricted entry interval (REI) is defined as the duration of time which must elapse before residues decline to a level so entry into a previously treated area and engaging in a specific task or activity would not result in exposures which exceed the Agency's level of concern. The restricted entry interval for oxyfluorfen is currently set at 24 hours based on its acute toxicity categories.

One study (MRID 420983-01), which measured the Dislodgeable Foliar Residue (DFR) of oxyfluorfen applied to conifer seedlings, was submitted. This study has serious deficiencies which include very low recovery, very high fortification levels, lack of method validation data and use of a non-standard dislodging solution. An attempt was made to account for these deficiencies by applying correction factors. Even with these correction factors, the study data indicates faster dissipation rates (90% for day 0 to day 1 and 34% after day 1) than the default value of 10%. This DFR study is sufficient to make an interim regulatory decision. However, confirmatory data are required.

Because chemical specific DFR data was not provided for bulb vegetables, the default initial deposition (20% of applied amount) and dissipation (10% per day) values were used.

7.2.1 Transfer Coefficients

The transfer coefficients used in this assessment are from an interim transfer coefficient policy developed by HED's Science Advisory Council for Exposure using proprietary data from the Agricultural Re-entry Task Force (ARTF) database (policy # 3.1). It is the intention of HED's Science Advisory Council for Exposure that this policy will be periodically updated to incorporate additional information about agricultural practices in crops and new data on transfer coefficients. Much of this information will originate from exposure studies currently being conducted by the ARTF, from further analysis of studies already submitted to the Agency, and from studies in the published scientific literature. These coefficients range from 300 for low contact activities such as scouting, irrigating and thinning immature fields of bulb vegetables to 3000 for higher contact activities such as shearing Christmas trees. The exact transfer coefficient for a given scenario also depends upon the crop height and foliage development. Currently there are no transfer coefficients for conifer seedlings or nursery plants listed in policy #3.1 and a value of 1000 cm^2/hr was chosen for conifer seedling irrigation/scouting based upon professional judgement, transfer coefficients for similar activities on other low crops, and preliminary ARTF data that is being collected for a variety of crops to include nursery plants. The risks calculated for conifer seedlings should be considered preliminary estimates until the ARTF data has been reviewed.

Table 18 - Post Application Exposure Scenarios and Transfer Coefficients		
Crop Type (Specific Crops)	**Post Application Exposure Scenarios**	**Transfer Coefficient (cm^2/hr)**
Berry, Low (Strawberries)	None - Applied to ground between rows prevent crop leaf contact	N/A
Field row crop, low/medium (Soybeans, Garbanzo beans, Cotton, Mint)	None - Applied to mint during dormant season and to garbanzo beans pre-emergence (crop and weed). Applied to cotton fields using branch lifters or shields to prevent contact with crop. Applied to soybean fields using flat fan nozzles positioned to prevent crop contact.	N/A
Field Corn	None - Spray is directed to base of corn plant to prevent leaf contact and injury.	N/A
Ornamentals (Cut Flowers)	None - Applied when leaves are dry and watered in to remove granules from leaves.	N/A
Trees, Deciduous and Citrus - Non-Bearing (Citrus, Apples, peaches pears etc)	None - Applied to orchard floor to avoid contact with leaves or green bark.	N/A
Trees, Conifer Seedlings (Can be applied over the top as conifer seedlings more than five weeks old are resistant to oxyfluorfen)	Irrigation, scouting, hand weeding escaped weeds	1000
Trees, Conifers	Irrigation, scouting Shearing	1000 3000
Tree Nut/Bean (Almonds, Coffee)	None - Applied to orchard floors	N/A
Bulb Vegetables (Garlic, Onions)	Irrigation, scouting, weeding,	300
Brassica (Broccoli, Cabbage, Cauliflower)	Could not be assessed - Applied to soil prior to transplanting. Transplants have to be inserted with minimal soil disturbance to maintain herbicidal activity. The Agency currently has no method for assessing dermal exposures from soil.	N/A
Artichoke	None - Applied to winter irrigation ditches or to bed furrows and shoulders at layby (see USDA Crop Profile)	N/A
Taro	None - Spray is directed to base of taro plant to prevent leaf contact and injury	N/A
Vine, Trellis (Grapes, Kiwi)	None - Applied to vineyard floors to avoid plant contact.	N/A

The calculations used to estimate the exposures for the post-application scenarios are similar to those described previously for the handler/applicator scenarios. Daily dermal exposure is calculated by multiplying the residue level (µg/cm^2 of leaf area) times a transfer coefficient (amount of leaf area contacted per unit time). Inhalation exposures were not calculated for the post-application scenarios because inhalation exposures have been shown to account for a negligible percentage of the overall body burden. This is particularly true for oxyfluorfen which has a very low vapor pressure (2×10^{-7} torr at 20°C).

The following assumptions were made regarding post application occupational exposure:

- Non-Cancer risks were assessed using the maximum label rates.
- Intermediate term non-cancer risks were assessed using average application rates.
- Cancer risks were assessed using the average application rates.
- The risks for conifer trees was also assessed at the rate (0.375 lb ai/acre) used for "chemical mowing" on Christmas trees in North Carolina.
- A private grower works at a single farm and has ten days of post application exposure per year.
- A commercial re-entry worker works at multiple farms and has thirty days of post application exposure per year.
- With the exception of conifers and bulb vegetables, applications would be made in such a way as to minimize contact with crop foliage (see Table 18).
- The initial percent of application rate as Dislodgeable Foliar Residue (DFR) was assumed to be 20% for bulb vegetables and the dissipation rate per day was assumed to be 10%. These are the standard values used in the absence of chemical specific data.
- The initial percent DFR for conifers was assumed to be either the standard value (20%).
- The dissipation rate per day for conifers was assumed to be either the standard value (10%) or the study values (90% for day zero to day 1, 34% after day 1).

7.2.2 - Exposure and Risk Estimates for Non-Cancer Effects

Estimated occupational post-application exposures and non-cancer risks were calculated and detailed results are presented in Appendix C. The length of time for the risks to decline to levels that are not of concern (i.e., the MOEs rise to 100 for ST and to 300 for IT) were also calculated and are included in Table 19. Only the length of time for Christmas tree shearing is longer than the restricted entry interval (REI) of 24 hours when using default assumptions. If the study data is used, dissipation occurs at a much greater rate which causes the MOEs to rise to above 300 by DAT one for the highest exposure scenario (Christmas tree shearing). If the lower application rate for chemical mowing is used, the MOEs rise to above 300 by DAT 0 with both default assumptions and study data.

It is understood that oxyfluorfen is applied to weeds in Christmas tree plantations in a semi-directed manner to reduce tree contact and that only the lower branches typically receive overspray. Therefore, the risk estimates for Christmas tree shearing are probably conservative.

Table 19 - Oxyfluorfen Post Application Non-Cancer Risks					
Crops	Application Rate	Input Values	Post Application Activities	DAT When ST MOE >100	DAT Where IT MOE >300
Bulb Vegetables	0.5/0.25	Default	Irrigation, scouting, weeding	0	0
Conifer Seedlings	1.0/0.5	Default	Irrigation, scouting, hand weeding escaped weeds	0	0
Conifer Seedlings	1.0/0.5	Study Data	Irrigation, scouting, hand weeding escaped weeds	0	0
Conifer Trees	2.0/1.0	Default	Irrigation, scouting Shearing	0 1	0 3
Conifer Trees	0.375	Default	Irrigation, scouting Shearing	0 0	0 0
Conifer Trees	2.0/1.0	Study Data	Irrigation, scouting Shearing	0 1	0 1
Conifer Trees	0.375	Study Data	Irrigation, scouting Shearing	0 0	0 0

***DAT = Day after treatment**
*Maximum label rates are used for short term (ST) risks while average rates are used for intermediate term (IT) risks

7.2.3 - Exposure and Risk Estimates for Cancer

A summary of the cancer risks for commercial re-entry workers is presented in Table 20. The risks for conifer tree activities exceed 1×10^{-4} on DAT zero when using either default assumptions or study data. These risks decline to less than 1.0×10^{-4} in 4 to 14 days when using default assumptions or 1 day when using study data. If the "Chemical Mowing" application rate is used, the cancer risk for Christmas tree shearing declines to less than 1.0×10^{-4} on DAT 5 when default data is used or on DAT 1 if study data is used. All of the scenarios have cancer risks in excess of 1.0×10^{-6} on day zero and the time for these risks to decline to 1.0×10^{-6} ranges from 23 to 58 days when using default assumptions and 6 to 11 days when using study data.

Table 20 - Post Application Cancer Risks for Commercial Workers					
Crops	Assumptions Used	Application Rate (lbs ai/acre)	Activities (Cancer Risk on Day Zero After Treatment)	DAT When Cancer Risk is Less Than:	
				1.0×10^{-4}	1.0×10^{-6}
Bulb Vegetables	Default	0.25	Irrigating, scouting hand weeding (2.1×10^{-5})	0	23
Tree Seedlings, Conifer	Default	0.5	Irrigation, Scouting, Hand Weeding (6.9×10^{-5})	0	41

Table 20 - Post Application Cancer Risks for Commercial Workers					
Crops	Assumptions Used	Application Rate (lbs ai/acre)	Activities (Cancer Risk on Day Zero After Treatment)	DAT When Cancer Risk is Less Than:	
				1.0×10^{-4}	1.0×10^{-6}
Tree Seedlings, Conifer	Study Data	0.5	Irrigation, Scouting, Hand Weeding (6.9×10^{-5})	0	6
Trees, Conifer	Default	1.0	Irrigation, Scouting (1.4×10^{-4}) Shearing (4.2×10^{-4})	4 14	47 58
Trees, Conifer	Default	0.375	Irrigation, Scouting (5.2×10^{-5}) Shearing (1.6×10^{-4})	0 5	38 48
Trees, Conifer	Study Data	1.0	Irrigation, Scouting (1.4×10^{-4}) Shearing (4.2×10^{-4})	1 1	8 11
Trees, Conifer	Study Data	0.375	Irrigation, Scouting (5.2×10^{-5}) Shearing (1.6×10^{-4})	0 1	6 8

Cancer risks for private growers are summarized in Table 21. The Christmas tree shearing scenario exceeds 1×10^{-4} on day zero when using either default assumptions or study data. These risks decline to less than 1.0×10^{-4} by DAT 1 if study data is used or by DAT 4 if default data is used. All of the private grower risks decline to less than 1.0X 10^{-6} in 12 to 47 days when using default data and 3 to 8 days when using study data. If the "Chemical Mowing" application rate is used, the cancer risk for Christmas tree shearing is less than less than 1.0×10^{-4} on DAT 0. . The equations used in these calculations and a more detailed listing of the results are contained in Appendix C.

Table 21 - Post Application Cancer Risk Summary for Private Growers					
Crops	Assumptions	Application Rate (lbs ai/acre)	Activity (Cancer Risk on Day Zero After Treatment)	DAT When Cancer Risk is Less Than:	
				1.0×10^{-4}	1.0×10^{-6}
Bulb Vegetables	Default	0.25	Irrigate and scout immature plants (3.5×10^{-6})	0	12
Tree Seedlings, Conifer	Default	0.5	Irrigation, Scouting, Hand Weeding (2.3×10^{-5})	0	30
Tree Seedlings, Conifer	Study Data	0.5	Irrigation, Scouting, Hand Weeding (2.3×10^{-5})	0	4
Trees, Conifer	Default	1.0	Irrigation, Scouting, Hand Weeding (4.6×10^{-5}) Shearing (1.4×10^{-4})	0 4	37 47
Trees, Conifer	Default	0.375	Irrigation, Scouting, Hand Weeding (1.7×10^{-5}) Shearing (5.2×10^{-5})	0 0	28 38
Trees, Conifer	Study Data	1.0	Irrigation, Scouting, Hand Weeding (4.6×10^{-5}) Shearing (1.4×10^{-4})	0 1	5 8

Table 21 - Post Application Cancer Risk Summary for Private Growers					
Crops	Assumptions	Application Rate (lbs ai/acre)	Activity (Cancer Risk on Day Zero After Treatment)	DAT When Cancer Risk is Less Than:	
				1.0×10^{-4}	1.0×10^{-6}
Trees, Conifer	Study Data	0.375	Irrigation, Scouting, Hand Weeding (1.7×10^{-5}) Shearing (5.2×10^{-5})	0 0	3 6

7.3 Incident Report

The incident report was prepared under a separate memo by Monica Spann, M.P.H. through Jerome Blondell, PhD. of the Office of Pesticide Programs and is enclosed in Appendix E. A total of 66 incidents were reported in the OPP Incident Data System (IDS) from 1994 to 2000. Most of these incidents involved irritant effects to the eyes, skin and occasionally respiratory passages and there was no medical evidence supplied to support the finding that these effects were anything other than coincidental to oxyfluorfen exposure. There were 25 cases reported in the California Pesticide Illness Surveillance Program and the majority of these cases involved minor symptoms of systemic illness such as headache, dizziness and nausea. During one of these incidents, nine of 15 field workers developed symptoms while transplanting cauliflower plants in a field that was sprayed about 30 minutes earlier. The reentry interval required on the label was 24 hours. These illnesses included symptoms of chemical conjunctivitis, eye irritation, tingling and itching of the left thigh, nausea, dizziness, headache, and vomiting.

The incident report recommends that measures be taken to enforce the reentry interval and that skin and eye protection be worn by handlers and those who are likely to have substantial contact with oxyfluorfen.

8.0 Data Needs/Label Requirements

- A 21-day dermal toxicity study in rats using the 98% a.i. formulation is required.
- Additional residue data and/or label revisions are required for bananas, cacao beans, soybean forage, and soybean hay.
- The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS 860.1000). As a result of changes to Table 1, additional oxyfluorfen residue data are now required for some commodities; these data requirements have been incorporated into the Product and Residue Chemistry Chapter. These new data requirements will be imposed at the issuance of the Oxyfluorfen RED but do not impinge on the reregistration eligibility decisions for oxyfluorfen. The need for additional tolerances and for revisions to dietary exposure/risk assessments will be determined upon receipt of the

required residue chemistry data.

- Acquisition of the following information will improve the non-dietary exposure assessment.
  - Frequency and timing of re-entry worker post application exposure following oxyfluorfen application to bulb vegetables.
  - Acceptable DFR data for oxyfluorfen applied to conifers at label rates. This data is needed to confirm the conclusions drawn from the submitted study which has serious deficiencies.
  - Case specific information regarding the exposure incidents that occurred in California.

List of Appendices

Appendix A	Toxicity Profile Tables
Appendix B	Occupational Handler Exposure and Risk Assessment Tables
Appendix C	Post-Application Worker Exposure and Risk Assessment Tables
Appendix D	Residential Handler Exposure and Risk Assessment Tables
Appendix E	Post-Application Residential Exposure and Risk Assessment Tables
Appendix F	Residue Chemistry Tolerance Reassessment

Appendix

APPENDIX A

Toxicity Profile Tables

Table 1. Toxicity Profile for Oxyfluorfen

Guideline No. / Study Type / % a.i.	MRID (year) / Classification / Doses	Results
870.3100 90-Day oral toxicity - rats 98.0%	44933101 (**1997**) acceptable/guideline 0, 500,1500,6000,10000 ppm M: 0, 46.7, 143.5, 585.0, 1012.1 mg/kg/d F: 0, 50.4, 150.5, 643.8, 1058.6 mg/kg/d	NOAEL = 1500 ppm (M: 143.5 mg/kg/day; F: 150.5 mg/kg/day LOAEL = 6000 ppm (M: 585.0 mg/kg/day; F: 643.8 mg/kg/day) based on decreased BW, increased urine volume, decreased erythrocyte volume and Hb, increased rel. liver wt
870.3100 90-Day oral toxicity - rats 72.5%	00117601 (**1982, Rohm & Haas**), 92136011, 42142317 acceptable/guideline 0, 800, 1600, 3200 ppm M: 0, 51.4, 105, 234 mg/kg/day F: 0, 61, 61.1, 124, 260 mg/kg/day	NOAEL < 800 ppm (M: 51.4 mg/kg/day; F: 61.1 mg/kg/day) LOAEL ≤ 800 ppm (M: 51.4 mg/kg/day; F: 61.1 mg/kg/day) based on increased liver wt and liver histopathology (M: hypertrophy; eosinophilia; and hepatic necrosis in 3 males) and adrenal histopathology (M, F)
870.3100 90-Day oral toxicity - rats 72%	00117603 (**1982, Nomura Institute**) acceptable/guideline 0, 200, 1000, 5000 ppm M: 14, 71, 361 mg/kg/day F: 18, 75, 396 mg/kg/day	NOAEL = 200 ppm (M: 14 mg/kg/day; F: 18 mg/kg/day) LOAEL = 1000 ppm (M: 71 mg/kg/day; F: 75 mg/kg/day) based on brown livers and kidneys, increased relative liver wt (M), decreased absolute/relative thymus wt (M), liver and kidney histopathology (slight)
870.3100 90-Day oral toxicity - mice 72.5%	0017602 (**1982**), 92136012, 42142316 acceptable/guideline 0, 200, 800, 3200 ppm M: 0, 32.0,134.5, 490.5 mg/kg/day F: 0, 44.4, 166.6, 520.9 mg/kg/day	NOAEL < 200 ppm (M: 32.0 mg/kg/day; F: 44.4 mg/kg/day LOAEL ≤ 200 ppm (M: 32.0 mg/kg/day; F: 44.4 mg/kg/day based on anemia increased SGPT, increased liver wt, liver histopathology MFO activity determined in this study.

Table 1. Toxicity Profile for Oxyfluorfen

Guideline No. / Study Type / % a.i.	MRID (year) / Classification / Doses	Results
870.3200 28-day dermal toxicity - rabbits technical 75% EC 31.7%	00071915 (**1978**), 92136014. **unacceptable** tech: 1500 mg/kg/day EC: 24.2, 96.8 mg/kg/day solvent control: 0.4 mL/kg/day	NOAEL for technical not defined LOAEL for technical = 1500 mg/kg/day based on decreased BW, increased liver wt, and microscopic hepatic hypertrophy in 1/4 animals in males and females NOAEL for EC formulation = 24.2 mg/kg/day LOAEL for EC formulation = 96.2 mg/kg/day based on decreased BW NOAEL for solvent control not defined LOAEL for solvent control = 0.4 mL/kg based on decreased BW dermal toxicity occurred in all treatment groups (erythema, dryness, edema)
(870.3465) non-guideline 1-month inhalation toxicity 23.5%	00071916 (**1978**), 000163582, 163584. **unacceptable** 0, 0 (vehicle control), 0.13, 0.65 mg/L M: 33.2 and 166.1 mg/kg/day F: 34.9, 174.7 mg/kg/day	NOAEL < 0.13 mg/L (M: 33.2 mg/kg/day; F: 34.9 mg/kg/day LOAEL ≤ 0.13 mg/L (M: 33.2 mg/kg/day; F: 34.9 mg/kg/day based on increased liver wt in low-dose females, but not high-dose females, lung pathology. Low-dose group sometimes showed more toxicity than high-dose group, many problems with this study.
870.3700a Developmental - rats 98.0%	44933103 (**1997**) acceptable/guideline 0, 375, 750, 1000 mg/kg/day	Maternal NOAEL ≥ 1000 mg/kg/day (HDT) Maternal LOAEL > 1000 mg/kg/day (HDT) Developmental NOAEL ≥ 1000 mg/kg/day (HDT) Developmental LOAEL > 1000 mg/kg/day (HDT)

Table 1. Toxicity Profile for Oxyfluorfen

Guideline No. / Study Type / % a.i.	MRID (year) / Classification / Doses	Results
870.3700a Developmental - rats 71.4%	41806501 **(1991)** acceptable/non-guideline 0, 18, 183, 848 mg/kg/day	Maternal NOAEL = 18 mg/kg/day Maternal LOAEL = 183 mg/kg/day based on clinical signs (red vaginal discharge, scant feces). At 848 mg/kg/day, increase incidence of maternal mortality. Developmental NOAEL = 18 mg/kg/day Developmental LOAEL = 183 mg/kg/day based on increased early resorptions, decreased fetal BW, vessel variations, bent scapula, fused sternebrae, bent bones in fore- and hindlimbs
870.3700b Developmental - rabbits 98.0%	44933102 (**1997**) acceptable/non-guideline 0, 10, 30, 90 mg/kg/day	Maternal NOAEL = 30 mg/kg/day Maternal LOAEL = 90 mg/kg/day based on abortions, clinical signs (loose feces, thin build), decreased FC, decreased gravid uterine wt Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 90 mg/kg/day based on increased late resorptions, decreased live fetuses/doe
870.3700b Developmental - rabbits 26.9% WP formulation	00094052 (**1981**), 00094051, 92136018, 92136019 acceptable/guideline 0, 0 (vehicle), 10, 30, 90 mg/kg/day	Maternal NOAEL = 10 mg/kg/day Maternal LOAEL = 30 mg/kg/day based on decreased BW gain and clinical signs (anorexia, red exudate). At 90 mg/kg/day, also increased maternal mortality, abortions, hematuria, decreased motor activity Developmental NOAEL = 30 mg/kg/day Developmental LOAEL = 90 mg/kg/day based on decreased litter size and increased early resorptions

Table 1. Toxicity Profile for Oxyfluorfen

Guideline No. / Study Type / % a.i.	MRID (year) / Classification / Doses	Results
870.3800 Reproduction - rats 71.4%	42014901 (**1991**) acceptable/guideline 0, 100, 400, 1600 ppm M: 0, 7.8, 30.9, 120 mg/kg/day F: 0, 8.5, 32.8, 131.2 mg/kg/day	Parental NOAEL = 400 ppm (M: 31; F: 33 mg/kg/day) Parental LOAEL = 1600 ppm (M: 120; F: 131 mg/kg/day) based on mortality, decreased BW, and liver and kidney histopathology (hepatocellular hypertrophy, renal pelvic mineralization, etc) Offspring NOAEL = 400 ppm (M: 31; F: 33 mg/kg/day) Offspring LOAEL = 1600 ppm (M: 120; F: 131 mg/kg/day) based on decreased BW/smaller litter size
870.4100b Chronic toxicity dogs 71.4-73.8%	00078767 (**1981**), 92136062, 92136016 acceptable/guideline 0, 100, 600, 2000 ppm M: 0, 3.1, 18.5, 61.0 mg/kgday F: 0, 3.0, 18.8, 60.3 mg/kg/day	NOAEL = 100 ppm (M: 3.1 mg/kg/day; F: 3.0 mg/kg/day) LOAEL = 600 ppm (M: 18.5 mg/kg/day; F: 18.8 mg/kg/day) based on decreased BW gains, increased SAP, increased liver wt
870.4300 combined chronic toxicity/ carcinogenicity - rats 85.7%	00083445 (**1978**), 00135072, 92136061 **unacceptable** 0, 2, 40, 800/1600 ppm M: 0, 0.1, 1.94, 56.96 mg/kg/day F: 0, 0.12, 2.43, 72.57 mg/kg/day	NOAEL $\geq$ 800/1600 ppm (M: 56.96 mg/kg/day; F: 72.57 mg/kg/day) LOAEL > 800/1600 ppm (M: 56.96 mg/kg/day; F: 72.57 mg/kg/day). No toxicity, no neoplasia
870.4200 Carcinogenicity mice 87.5%	00037939 (**1977**), 92136017 **acceptable** 0, 0 (ethanol), 2, 20, 200 ppm M: 0, 0 (ethanol), 0.3, 3.0, 33 mg/kg/day F: 0, 0 (ethanol), 0.4, 4.0, 42.0 mg/kg/day	NOAEL = 20 ppm (M: 3.0; F: 4.0 mg/kg/day) LOAEL = 200 ppm (M: 33; F: 42 mg/kg/day) based on increased liver wt, increased SAP and SGPT, liver histopathology (including hepatocyte necrosis) **Combined adenomas/carcinomas increased: used to set Q_1***

Table 1. Toxicity Profile for Oxyfluorfen

Guideline No. / Study Type / % a.i.	MRID (year) / Classification / Doses	Results
870.7485 Metabolism and pharmacokinetics	42374201 (1992) 42652401 (1993)	Rapidly absorbed, extensively metabolized, and rapidly eliminated. Most compound eliminated in the feces; females eliminated more in the urine than did males.
870.7600 Dermal penetration	42142306 (1989), 92136095 acceptable	Maximal absorption = 18% at LDT when compound remaining on skin is considered potentially absorbable.

ABBREVIATIONS:
M = Male, F = Female, BW = body weight
SAP = serum alkaline phosphatase enzyme
SGPT = serum glutamate pyruvate transaminase enzyme or ALT
Hb = hemoglobin, PT = prothrombin time
MFO = mixed function oxidase
EC = emulsifiable concentrate formulation, WP = wettable powder formulation
LDT = lowest dose tested in study.

Table 2. Genetic Toxicity Profile for Oxyfluorfen (96-99 %)

Assay	Test Material			MRID No.	Result
	ID	Lot No.	Purity (%)		
Ames	RH-2915	TTF068	99.7	00098421	Neg. to HDT (7500 µg/plate); no ppt.
Mouse Lymphoma	RH-2915	0453	99.7	00098419	Neg; ppt at ≥62.5 µg/mL
Ames [a]	AG 510 Tech.	252/1	96	44942801	**Pos. TA 100 at high insoluble doses (≥1667 µg/plate +S9)**
Ames [a]	AG 510 Tech.	252/1	96	44933104	Neg to HDT (5000 µg/plate); insoluble at this level
Mouse Micronucleus	AG 510 Tech.	P-8	96	44933105	Neg to HDT (2000 mg/kg, ip); cytotoxic to bone marrow
In vivo Rat UDS	AG 510 Tech.	P-8	96	44933106	Neg to HDT (2000 mg/kg)
Ames	Goal Herb	NA	99.2	44947206	Neg; unacceptable but upgradable
Mouse Lymphoma	Goal Tech Herb	NA	97.1	44947202	Neg; ppt. not reported
CHO/HGPRT	Goal Tech Purified Herb	NA	99.2	44947205	Neg; ppt at ≥50 µg/mL
CHO/Chromo Aberrations	Goal Tech Purified Herb	NA	99.2	44947204	Neg; ppt at ≥450 µg/mL
In vivo Mouse Cytogenetics	Goal Tech Purified Herb	NA	97.1	44947203	Neg to HDT (5000 mg/kg)
Bacterial DNA Damage/Repair	Goal Tech Herb	NA	97.1	44947201	Neg; ppt. at 1000 µg/plate

[a] The two Ames studies were conducted in different contract laboratories; each protocol required the performance of two independent trials.

Abbreviations:

HDT = Highest dose tested ppt = precipitation ip = intraperitoneal NA = not available

This table is from the HIARC report dated 4/23/01.

Table 3. Genetic Toxicity Profile for Oxyfluorfen (71 %)

Assay	Test Material	MRID No.	Result

	ID	Lot No.	Purity (%)		
Ames	Goal Herb Tech	AMB18-42A	71.4	40992201	**Pos strains TA98 & TA100 at insoluble (≥1600 µg/plate +S9) and soluble (900 µg/plate +S9) doses; weak unconfirmed response -S9**
In vivo Rat Cytogenetics	Goal Herb Tech	2-0956	71.4	41873801	Neg to HDT (5 g/kg)
In vivo Rat Cytogenetics	Goal Herb Tech	2-3985	72.5	00098418	Neg up to lethal dose (1.19 mg/kg)
Ames	RH-2915	2-3985	72.7	00098420	**Pos. strain TA1537 (≥2500 µg/plate +S9; ≥6000 µg/mL -S9); TA98 (≥500 µg/plate +S9; ≥1000 µg/mL -S9); TA100 (≥250 µg/plate +S9; ≥2500 µg/mL -S9)**; no ppt reported
Mouse Lymphoma	RH-2915	2-3985	72.7	00109283	**Pos. 1.95-40 µg/mL +S9; no dose response; ppt at ≥62 µg/mL**
In vitro UDS Rat Hepato	RH-2915	7530	73	00098423	Neg to cytotox doses (25 µg/mL)
Ames	Polar fraction RH-2915, Lot #2-3985	WJZ 1861	NA	00098422	**Pos. (only tested TA98) ; 50-7500 µg/plate +/-S9 not dose related**; stronger response +S9
In vitro UDS Rat Hepato	Polar fraction RH-2915, Lot #2-3985	WJZ 1861	NA	00098424	Neg up to cytotox dose (25 µg/mL)

This table is from the HIARC report dated 4/23/01.

APPENDIX B

OXYFLUORFEN OCCUPATIONAL HANDLER EXPOSURE AND RISK ASSESSMENT TABLES

Table B1: Unit Exposure Data for Oxyfluorfen Occupational Exposure Assessment

Mitigation Levels[A]	Unit Exposure Values (Per lb Ai Handled)	Data Confidence[B]
Scenarios 1A, 2A , 3A , 4A , 5 and 6A - Mix/Load Liquids for Large Groundboom, Average Groundboom, ATV Groundboom, Aerial Fixed Wing , Chemigation and Right of Way Sprayer (PHED data)		
Baseline	Dermal = 2.9 mg Inhalation = 1.2 ug	Hand and dermal are AB grades, and inhalation are AB grades. Hand replicates =53 replicates; Dermal = 72 to 122 replicates; and inhalation = 85 replicates. High confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure.
Single Layer	Dermal = 0.023 mg Inhalation = 1.2 ug	The same dermal data and inhalation data are used as for baseline. Gloved hand data = AB grades, replicates = 59.
Double Layer	Dermal = 0.0175 mg Inhalation = 1.2 ug	The same dermal data are used as for baseline with a 50% protection factor to account for the use of an additional layer of clothing (i.e., coveralls or Tyvek suit). The same gloved hand data are used as for single layer. The same inhalation data are used as for the baseline.
Double Layer PF5	Dermal = 0.0175 mg Inhalation = 0.24 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PF10	Dermal = 0.0175 mg Inhalation = 0.12 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	Dermal = 0.0086 mg Inhalation = 0.083 ug	Hand and dermal unit exposure are AB grades. Hand = 31 replicates; and dermal = 16 to 22 replicates. High confidence in dermal and hand data. Inhalation data are AB grade; replicates = 27. High confidence in inhalation data.
Scenarios 1B, 2B and 3B - Spray Application , Large , Average and ATV Groundboom (PHED Data)		
Baseline	Dermal =0.014 mg Inhalation = 0.74 ug	Hand, dermal, and inhalation data = AB grades. Hand = 29 replicates; dermal = 23 to 42 replicates; and inhalation = 22 replicates. High confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure value.
Single Layer	Dermal = 0.014 mg Inhalation = 0.74 ug	The same dermal and inhalation data are used as for baseline. Gloved hand data are ABC grades, with 21 replicates, and medium confidence level.
Double Layer	Dermal = 0.011 mg Inhalation = 0.74 ug	The same dermal data are used as for baseline with a 50% protection factor to account for the use of an additional layer of clothing. Gloved hand data are ABC grades with 21 replicates and a medium confidence level. The same inhalation data are used as for the baseline.
Double Layer PF5	Dermal = 0.011 mg Inhalation = 0.15 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PF10	Dermal = 0.011 mg Inhalation = 0.074 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	Dermal = 0.005 mg Inhalation = 0.043 ug	Hand and dermal unit exposure are ABC grades. Hand =16 replicates; and dermal = 20-31 replicates. Medium confidence in dermal and hand data. Inhalation data are AB grade; replicates =16. High confidence in inhalation data. Gloves not worn.
Scenario 4B - Aerial Fixed Wing Spray Application , Closed Cockpit (PHED Data)		
Baseline	Dermal = 0.005 mg Inhalation = 0.068 ug	Hands = AB grade, dermal and inhalation=ABC grade. Hands=34 replicates; dermal =24 to 48 replicates, and inhalation =23 replicates. Medium Confidence in dermal and inhalation data; high confidence in hand data. No protection factor was needed to define the unit exposure value as no PPE is worn by pilots while airborne.
Scenario 4C - Flag Aerial Spray Applications (PHED data)		
Baseline	Dermal =0.011mg Inhalation = 0.35 ug	Hands, dermal and inhalation AB grades. Dermal =18 to 28 replicates; Hands =30 replicates; and inhalation=28 replicates. High confidence in dermal, hand, and inhalation data.
Single Layer	Dermal = 0.012 mg Inhalation = 0.35 ug	The same dermal and inhalation data are used as for baseline. Gloved hand data are AB grades with 6 replicates and low confidence.
Double Layer	Dermal = 0.011 mg Inhalation = 0.35 ug	The same dermal data are used as for baseline with a 50% protection factor to account for the use of an additional layer of clothing. The same gloved hand data are used as for single layer. The same inhalation data are used as for baseline.

Mitigation Levels[A]	Unit Exposure Values (Per lb Ai Handled)	Data Confidence[B]
Double Layer PF5	Dermal = 0.011 mg Inhalation = 0.070 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PF10	Dermal = 0.011 mg Inhalation = 0.035 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	Dermal = 0.00022 mg Inhalation = 0.007 ug	The same data are used as for baseline with a 98% protection factor to simulate closed cab.
Scenario 6B - Spray Application Using Right of Way Sprayer (PHED Data)		
Baseline	Dermal =1.3 mg Inhalation = 3.9 ug	Dermal = 4 - 20 replicates, ABC grades. Hand = 16 replicates, AB grade. Inhalation = 16 replicates, A grade. Low confidence in hand and dermal data due to low number of replicates. High confidence in inhalation data. No protection factor was needed to define the unit exposure value.
Single Layer	Dermal = 0.39 mg Inhalation = 3.9 ug	The same dermal and inhalation data are used as for baseline. Gloved hand data = 4 replicates, AB grade. Low confidence in hand data due to low number of replicates.
Double Layer	Dermal = 0.29 mg Inhalation = 3.9 ug	The same dermal data are used as for baseline with a 50% protection factor to account for the use of an additional layer of clothing. The same gloved hand data are used as for single layer. The same inhalation data are used as for baseline.
Double Layer PF5	Dermal = 0.29 mg Inhalation = 0.78 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PF10	Dermal = 0.29 mg Inhalation = 0.39 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	ND	No data is currently available for this scenario with engineering controls.
Scenario 7 - Mix/Load/Apply Liquids Using Backpack Sprayer (PHED Data)		
Baseline	Dermal = ND Inhalation = 30 ug	No data is available for dermal exposure. Inhalation = 11 replicates, A grade. Low confidence due to low number of replicates.
Single Layer	Dermal = 2.5 mg Inhalation = 30 ug	Dermal = 9 - 11 replicates, AB grades. Hand = 11 replicates, C grade. Same inhalation data are used as for baseline. Low confidence in dermal and hand data due to low number of replicates.
Double Layer	Dermal = 1.6 mg Inhalation = 30 ug	The same dermal data are used as for single layer PPE with a 50% protection factor to account for the use of an additional layer of clothing. The same gloved hand data are used as for single layer. The same inhalation data are used as for baseline.
Double Layer PF5	Dermal = 1.6 mg Inhalation = 6.0 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PF10	Dermal = 1.6 mg Inhalation = 3.0 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	ND	No data is currently available for this scenario with engineering controls.
Scenario 8A - Load Granules for Tractor Drawn Spreader (PHED Data)		
Baseline	Dermal = 0.0084 mg Inhalation = 1.7 ug	Dermal = 33 - 78 replicates, ABC grades. Hand = 10 replicates, All grade. Inhalation = 58 replicates, AB grade. Low confidence due to poor grade quality of hand replicates and low replicate number. High confidence in inhalation data. No protection factor was needed to define the unit exposure value.
Single Layer	Dermal = 0.0069 mg Inhalation = 1.7 ug	Dermal = 33 - 78 replicates, ABC grades. Gloved Hand = 45 replicates, AB grade. Medium confidence in dermal and hand data. Baseline inhalation data was used.
Double Layer	Dermal = 0.0034 mg Inhalation = 1.7 ug	Dermal = 12 - 59 replicates, ABC grades. Gloved Hand = 45 replicates, AB grade. Low confidence in dermal data due to low replicate number for many body parts. Baseline inhalation data was used.

Mitigation Levels[A]	Unit Exposure Values (Per lb Ai Handled)	Data Confidence[B]
Double Layer PP5	Dermal = 0.0034 mg Inhalation = 0.34 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PP10	Dermal = 0.0034 mg Inhalation = 0.17 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	Dermal = 0.00017 mg Inhalation = 0.034 ug	The same hand, dermal and inhalation data are used as for baseline with a 98% protection factor to account for the use of engineering controls.
Scenario 8B - Apply Granules with an Tractor Drawn Spreader (PHED Data)		
Baseline	Dermal = 0.0099 mg Inhalation = 1.2 ug	Dermal = 1-5 replicates, AB grades. Hand = 5 replicates, AB grade. Inhalation = 5 replicates, AB grade. Low confidence due to inadequate replicate number.
Single Layer	Dermal = 0.0072 mg Inhalation = 1.2 ug	Dermal = 1-5 replicates, AB grades. Low confidence due to inadequate replicate number. Hand data estimated from baseline with a 90% protection factor to account for the use of gloves. Baseline inhalation data was used with no protection factors.
Double Layer	Dermal = 0.0042 mg Inhalation = 1.2 ug	Dermal data estimated from baseline with a 50% protection factor to account for the use of coveralls. Hand data estimated from baseline with a 90% protection factor to account for the use of gloves. Baseline inhalation data was used with no protection factors.
Double Layer PF5	Dermal = 0.0042 mg Inhalation = 0.24 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PF10	Dermal = 0.0042 mg Inhalation = 0.12 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	Dermal = 0.0021 mg Inhalation = 0.22 ug	Dermal = 2 - 30 replicates, AB grade. Hand = 17 replicates, AB grade. Neck data has only two replicates. Other body parts have 27 - 30 replicates. High Confidence except for neck data. Inhalation = 37 replicates, AB grade. High Confidence.
Scenario 9 - Load/Apply Granules Using Push Type Broadcast Spreader (ORETF Data from OMA-001)		
Baseline	Dermal = 0.35 mg Inhalation = 7.5 ug	Dermal = 20 replicates, AB grades. Hand = 20 replicates, AB grade. Inhalation = 40 replicates, AB grade. High confidence in dermal, hand and inhalation data. No protection factor was needed to define the unit exposure value.
Single Layer	Dermal = 0.22 mg Inhalation = 7.5 ug	Dermal = 20 replicates, AB grades. Hand = 20 replicates, AB grade. Same inhalation data as for baseline. High confidence in dermal, hand and inhalation data. No protection factor was needed to define the unit exposure value.
Double Layer	Dermal = 0.11 mg Inhalation = 7.5 ug	The same hand and dermal data are used as for single layer with a 50% protection factor for the dermal data to account for the use of coveralls over single layer PPE. The same inhalation data are used as for baseline.
Double Layer PP5	Dermal = 0.11 mg Inhalation = 1.5 ug	Same as above with an 80% protection factor applied to baseline inhalation data to account for the use of a PF5 dust/mist respirator.
Double Layer PF10	Dermal = 0.11 mg Inhalation = 0.75 ug	Same as above with an 90% protection factor applied to baseline inhalation data to account for the use of a PF10 cartridge respirator.
Engineering Controls	ND	No data is currently available for this scenario with engineering controls.

Notes for Table 1

A Baseline - long pants, long sleeved shirt, no gloves, no respirator, open mixing/loading, open cab tractor for groundboom applications, and open flagging.
Single Layer - chemical resistant gloves, long pants, long sleeved shirt, hat and no respirator.
Double Layer - coveralls over single layer clothing, chemical resistant gloves .
Double Layer PF5 - Same as above with a PF5 Dust/mist respirator or dust mask
Double Layer PF10 - Same as above with a PF10 half face cartridge respirator
Engineering Controls - Includes closed mixing/loading and/or enclosed cab application

B Data confidence is based up the number of replicates and the quality of the data. Data grades are based on field and laboratory recovery data provided as part of the exposure studies. A replicate refers to data acquired during one complete work cycle. Data grades are assigned as follows:

Data Grade	% Lab Recovery	CV for Lab Recovery	% Field Recovery	% Storage Stability	Data Corrected for:
A	90-110	$\leq$15	70-120	Not Needed	Field Recovery (If <90%)
B	80-110	$\leq$25	50-120	Not Needed	Field Recovery
C	70-120 70-120	$\leq$33 $\leq$33	30-120 Missing	Not Needed 50-120	Field Recovery Storage Stability
D	60-120	$\leq$33	Not Needed	Not Needed	Field recovery, storage stability or lab recovery
E	Does not meet above criteria				

These data grades are combined with the number of replicates to determine the confidence of each data set as follows:

High confidence run - grades A and B data <u>and</u> 15 or more replicates per body part.
Medium confidence run - grades A, B, and C data <u>and</u> 15 or more replicates per body part.
Low confidence run - all grades (any run that includes D or E grade data) <u>or</u> has less than 15 replicates per body part.

Table B2: Agricultural Application Rates and Methods for Oxyfluorfen

Application Method	Crops Treated	Maximum Application Rate (lb ai/acre)	Average Application Rate	Area Treated (Acre/day)	Comments
1 - Large Groundboom	Cotton, soybeans Corn (witchweed control program)	0.5 0.75	0.25 0.50	200 200	
2 - Average Groundboom	Onions, garlic, horseradish, garbanzo bean Broccoli, Cabbage, Cauliflower Mint (dormant) Trees, nursery (seedbeds, transplants, container stock) Orchard Floors (almonds, coffee) Vineyard floors (grape)	0.5 0.5 2.0 2.0 2.0 2.0	0.25 0.25 0.40 1.0 1.0 1.0	80 80 80 80 80 80	
3 - ATV Groundboom	Artichoke	2.0	1.0	40	Spray Volume = 40 gallons/acre
4 - Fixed Wing Aircraft	Fallow beds	0.5	0.25	1200	Primarily fallow cotton fields
5 - Chemigation	Onions, Garlic, Horseradish	0.5	0.25	350	
6 - Right of Way Sprayer	Right of Way Areas	2.0	1.0	25	1000 gallons/day 40 gallons per acre
7 - Backpack Sprayer	Conifer Plantations Using Label Rates	2.0	1.0	2	40 gallons/day 20 gallons per acre
7 - Backpack Sprayer	Conifer Plantations Using Lower Rates for Chemical Mowing	0.375	0.375	2	40 gallons/day 20 gallons per acre
8 - Tractor Drawn Broadcast Spreader	Ornamentals, container, field grown and landscape	2.0	1.0	40	
9- Broadcast Spreader	Ornamentals, container, field grown and landscape	2.0	1.0	5	

Notes

1. Maximum Application Rates are taken from the labels and are used for calculation of non-cancer risks
2. Average Application rates are taken from the Quantitative Use Report for Oxyfluorfen of June 5, 2001 and are used for the calculation of cancer risks.
3. Treated areas are from the HED Science Advisory Council for Exposure Policy #009 " Standard Values for Daily Acres Treated in Agriculture"

Table B3: Baseline Clothing Oxyfluorfen Worker Exposure and Risks (Non-Cancer, Short-Term)

Exposure Scenario	Typical Crops	Label Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Absorbed Daily Dose (mg/kg/day)[c]	Combined MOE[d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.75	200	435	0.18	1.3	0.0030	1.3	**22.9**
1B - Spray Application - Large Groundboom				2.1	0.11	0.006	0.0019	0.008	3681
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.5	200	290	0.12	0.87	0.0020	0.87	**34**
1B - Spray Application - Large Groundboom				1.4	0.07	0.004	0.0012	0.005	5521
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	2.0	80	464	0.19	1.4	0.0032	1.4	**22**
2B - Spray Application - Average Groundboom				2.2	0.12	0.0067	0.0020	0.0087	3451
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.5	80	116	0.048	0.35	0.0008	0.35	**86**
2B - Spray Application - Average Groundboom				0.56	0.030	0.0017	0.0005	0.0022	13804
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	2.0	40	232	0.096	0.70	0.0016	0.70	**43**
3B - Spray Application - ATV Groundboom				1.1	0.059	0.0034	0.00099	0.0043	6902
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.50	1200	1740	0.720	5.2	0.01200	5.2	**5.7**
4B - Spray Application - Fixed-Wing Aircraft				3.0	0.041	0.0090	0.00068	0.0097	3099
4C - Flag Aerial Applications				6.6	0.21	0.0198	0.00350	0.0233	1288
5 - Mix/Load Liquids for Chemigation	Onion, Garlic, Horseradish	0.5	350	508	0.21	1.52	0.00350	1.5	**20**
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	2.0	25	145	0.06	0.44	0.00100	0.4	**69**
6B - Spray Application - Right of Way Sprayer				65	0.20	0.20	0.00325	0.20	151
7 - Mix/Load/Apply Liquids - Backpack	Conifers	2.0	2	No Data for This Scenario					
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	No Data for This Scenario					
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	2.0	40	0.67	0.136	0.0020	0.00227	0.0043	7005
8B - Tractor Drawn Spreader - Apply	Ornamentals	2.0	40	0.79	0.096	0.0024	0.00160	0.0040	7545
9 - Push Type Broadcast Spreader (Load/Apply)	Ornamentals	2.0	5	3.5	0.075	0.0105	0.00125	0.0118	2553

Notes for this table follow Table B4.

Table B4: Single Layer PPE w/o Respirator Oxyfluorfen Worker Exposure and Risks (Non-Cancer, Short-Term)

Exposure Scenario	Crops	Label Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Absorbed Daily Dose (mg/kg/day)[c]	Combined MOE[d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.75	200	3.5	0.180	0.0104	0.00300	0.0134	2247
1B - Spray Application - Large Groundboom				2.1	0.111	0.0063	0.00185	0.0082	3681
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.5	200	2.3	0.120	0.0069	0.00200	0.0089	3371
1B - Spray Application - Large Groundboom				1.4	0.074	0.0042	0.00123	0.0054	5521
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	2.0	80	3.7	0.192	0.0110	0.00320	0.0142	2107
2B - Spray Application - Average Groundboom				2.2	0.118	0.0067	0.00197	0.0087	3451
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.5	80	0.92	0.048	0.0028	0.00080	0.0036	8427
2B - Spray Application - Average Groundboom				0.56	0.030	0.0017	0.00049	0.0022	13804
3A - Mix/Load Liquids -ATV Groundboom	Artichokes	2.0	40	1.8	0.096	0.0055	0.00160	0.0071	4213
3B - Spray Application - ATV Groundboom				1.1	0.059	0.0034	0.00099	0.0043	6902
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.50	1200	13.8	0.720	0.0414	0.01200	0.0534	562
4B - Spray Application - Fixed-Wing Aircraft				ND - Gloves are not worn during aerial application					
4C - Flag Aerial Applications				7.2	0.210	0.022	0.00350	0.025	1195
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.50	350	4.0	0.210	0.012	0.00350	0.016	1926
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	2.0	25	1.2	0.060	0.0035	0.00100	0.0045	6742
6B - Spray Application - Right of Way Sprayer				20	0.195	0.06	0.00325	0.06	486
7 - Mix/Load/Apply Liquids - Backpack	Conifers	2.0	2	10	0.120	0.030	0.00200	0.032	938
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.9	0.0225	0.0056	0.00038	0.0060	5000
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	2.0	40	0.55	0.136	0.0017	0.00227	0.0039	7648
8B - Tractor Drawn Spreader - Apply	Ornamentals	2.0	40	0.58	0.096	0.0017	0.00160	0.0033	9014
9 - Push Type Broadcast Spreader (Load/Apply)	Ornamentals	2.0	5	2.2	0.075	0.0066	0.00125	0.008	3822

Notes for Tables B3 and B4

a Daily Exposure (mg/day) = Application Rate (lb ai/Acre) * Treated Area (Acre/day) * Unit Exposure Value (mg or µg exposure/ lb ai handled) *[1mg/1000µg (conversion factor if necessary)].

b Absorbed Daily Dose (mg/kg/day) = Daily Exposure (mg/day) * Absorption Factor (0.18 for dermal; 1.0 for inhalation) ÷ Body Weight (60kg).

c Combined Absorbed Daily Dose (mg/kg/day) = Dermal Absorbed Daily Dose (mg/kg/day) + Inhalation Absorbed Daily Dose (mg/kg/day).

d MOE (unitless) = NOAEL (mg/kg/day) ÷ Combined Absorbed Daily Dose (mg/kg/day). Where NOAEL = 30 mg/kg/day for short-term exposures.
A Margin of Exposure (MOE) of 100 or greater is acceptable for Oxyfluorfen short term exposures.

Table B5: Baseline Clothing Oxyfluorfen Worker Exposure and Risks (Non-Cancer, Intermediate-Term)

Exposure Scenario	Crops	Label Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Absorbed Daily Dose (mg/kg/day)[c]	Combined MOE[d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.75	200	435	0.18	1.1	0.0026	1.1	**28.5**
1B - Spray Application - Large Groundboom				2.1	0.11	0.0054	0.0016	0.0070	4581
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.5	200	290	0.12	0.7	0.0017	0.7	**43**
1B - Spray Application - Large Groundboom				1.4	0.07	0.0036	0.0011	0.0047	6871
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	2.0	80	464	0.19	1.2	0.0027	1.2	**27**
2B - Spray Application - Average Groundboom				2.2	0.12	0.0058	0.0017	0.0075	4294
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.5	80	116	0.048	0.30	0.0007	0.30	**107**
2B - Spray Application - Average Groundboom				0.56	0.030	0.0014	0.0004	0.0019	17178
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	2.0	40	232	0.096	0.60	0.0014	0.60	**54**
3B - Spray Application - ATV Groundboom				1.1	0.059	0.0029	0.00085	0.0037	8589
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.50	1200	1740	0.720	4.5	0.01029	4.5	**7.1**
4B - Spray Application - Fixed-Wing Aircraft				3.0	0.041	0.0077	0.00058	0.0083	3857
4C - Flag Aerial Applications				6.6	0.21	0.0170	0.00300	0.0200	1602
5 - Mix/Load Liquids for Chemigation	Onion, Garlic, Horseradish	0.5	350	508	0.21	1.31	0.00300	1.3	**24**
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	2.0	25	145	0.06	0.37	0.00086	0.4	**86**
6B - Spray Application - Right of Way Sprayer				65	0.20	0.17	0.00279	0.17	**188**
7 - Mix/Load/Apply Liquids - Backpack	Conifers	2.0	2	No Data for This Scenario					
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	No Data for This Scenario					
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	2.0	40	0.67	0.136	0.0017	0.00194	0.0037	8717
8B - Tractor Drawn Spreader - Apply	Ornamentals	2.0	40	0.79	0.096	0.0020	0.00137	0.0034	9390
9 - Push Type Broadcast Spreader (Load/Apply)	Ornamentals	2.0	5	3.50	0.075	0.0090	0.00107	0.0101	3177

Notes for this table follow Table B6.

Table B6: Single Layer w/o Respirator Oxyfluorfen Worker Exposure and Risks (Non-Cancer, Intermediate-Term)

Exposure Scenario	Crops	Label Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Absorbed Daily Dose (mg/kg/day)[c]	Combined MOE[d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.75	200	3.5	0.180	0.0104	0.00300	0.0134	2397
1B - Spray Application - Large Groundboom				2.1	0.111	0.0063	0.00185	0.0082	3926
1A - Mix/Load Liquids - Large Groundboom	Soybeans, Cotton	0.5	200	2.3	0.120	0.0069	0.00200	0.0089	3596
1B - Spray Application - Large Groundboom				1.4	0.074	0.0042	0.00123	0.0054	5890
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	2.0	80	3.7	0.192	0.0110	0.00320	0.0142	2247
2B - Spray Application - Average Groundboom				2.2	0.118	0.0067	0.00197	0.0087	3681
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.5	80	0.9	0.048	0.0028	0.00080	0.0036	8989
2B - Spray Application - Average Groundboom				0.6	0.030	0.0017	0.00049	0.0022	14724
3A - Mix/Load Liquids -ATV Groundboom	Artichokes	2.0	40	1.8	0.096	0.0055	0.00160	0.0071	4494
3B - Spray Application - ATV Groundboom				1.1	0.059	0.0034	0.00099	0.0043	7362
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.50	1200	13.8	0.720	0.0414	0.01200	0.0534	599
4B - Spray Application - Fixed-Wing Aircraft				ND - Gloves are not worn during aerial application					
4C - Flag Aerial Applications				7.2	0.210	0.022	0.00350	0.025	1275
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.50	350	4.0	0.210	0.012	0.00350	0.016	2055
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	2.0	25	1.2	0.060	0.0035	0.00100	0.0045	7191
6B - Spray Application - Right of Way Sprayer				20	0.195	0.06	0.00325	0.06	518
7 - Mix/Load/Apply Liquids - Backpack	Conifers	2.0	2	10	0.120	0.030	0.00200	0.032	1000
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.9	0.0225	0.0056	0.00038	0.0060	5333
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	2.0	40	0.55	0.136	0.0017	0.00227	0.0039	8158
8B - Tractor Drawn Spreader - Apply	Ornamentals	2.0	40	0.58	0.096	0.0017	0.00160	0.0033	9615
9 - Push Type Broadcast Spreader (Load/Apply)	Ornamentals	2.0	5	2.2	0.075	0.0066	0.00125	0.008	4076

Notes for Tables B5 and B6

a Daily Exposure (mg/day) = Application Rate (lb ai/Acre) * Treated Area (Acre/day) * Unit Exposure Value (mg or µg exposure/ lb ai handled) *[1mg/1000µg (conversion factor if necessary)].

b Absorbed Daily Dose (mg/kg/day) = Daily Exposure (mg/day) * Absorption Factor (0.18 for dermal; 1.0 for inhalation) ÷ Body Weight (70kg).

c Combined Absorbed Daily Dose (mg/kg/day) = Dermal Absorbed Daily Dose (mg/kg/day) + Inhalation Absorbed Daily Dose (mg/kg/day).

d MOE (unitless) = NOAEL (mg/kg/day) ÷ Combined Absorbed Daily Dose (mg/kg/day). Where NOAEL = 32 mg/kg/day for intermediate-term exposures.
A Margin of Exposure (MOE) of 300 is acceptable for intermediate term exposures.

Table B7: Single Layer w/o Respirator Worker Exposure and Cancer Risk for Oxyfluorfen (30 days per Year)

Exposure Scenario	Crops	Average Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Lifetime Absorbed Daily Dose (mg/kg/day)[c]	Cancer Risk[d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	200	2.3	0.120	0.0059	0.00171	3.1e-04	2.3e-05
1B - Spray Application - Large Groundboom				1.4	0.074	0.0036	0.00106	1.9e-04	1.4e-05
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	200	1.2	0.060	0.0030	0.00086	1.6e-04	1.1e-05
1B - Spray Application - Large Groundboom				0.7	0.037	0.0018	0.00053	9.6e-05	7.0e-06
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	1.0	80	1.8	0.096	0.0047	0.00137	2.5e-04	1.8e-05
2B - Spray Application - Average Groundboom				1.1	0.059	0.0029	0.00085	1.5e-04	1.1e-05
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.25	80	0.46	0.024	0.0012	0.00034	6.3e-05	4.6e-06
2B - Spray Application - Average Groundboom				0.28	0.015	0.0007	0.00021	3.8e-05	2.8e-06
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	40	0.92	0.048	0.0024	0.00069	1.3e-04	9.2e-06
3B - Spray Application - ATV Groundboom				0.56	0.030	0.0014	0.00042	7.7e-05	5.6e-06
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.25	350	2.0	0.105	0.0052	0.00150	2.7e-04	2.0e-05
4B - Spray Application - Fixed-Wing Aircraft[e]				0.44	0.0060	0.0011	0.0001	5.0e-05	3.6e-06
4C - Flag Aerial Applications				1.1	0.031	0.0027	0.00044	1.3e-04	9.4e-06
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.25	350	2.0	0.105	0.0052	0.00150	2.7e-04	2.0e-05
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	1.0	25	0.6	0.030	0.0015	0.00043	7.8e-05	5.7e-06
6B - Spray Application - Right of Way Sprayer				10	0.098	0.025	0.00139	1.1e-03	8.0e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	2	5.0	0.060	0.013	0.00086	5.6e-04	4.1e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.9	0.023	0.005	0.00032	2.1e-04	1.5e-05
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	1.0	40	0.28	0.068	0.0007	0.00097	6.9e-05	5.1e-06
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	40	0.29	0.048	0.0007	0.00069	5.9e-05	4.3e-06
9 - Push Type Broadcast Spreader (Load/Apply)	Ornamentals	1.0	5	1.1	0.038	0.003	0.00054	1.4e-04	1.0e-05

Notes for this table follow Table B11.

Table B8: Double Layer w/o Respirator Worker Exposure and Cancer Risk for Oxyfluorfen (30 days per Year)

Exposure Scenario	Crops	Average Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Lifetime Absorbed Daily Dose (mg/kg/day)[c]	Cancer Risk [d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	200	1.8	0.120	0.0045	0.00171	2.6e-04	1.9e-05
1B - Spray Application - Large Groundboom				1.1	0.0740	0.0028	0.00106	1.6e-04	1.2e-05
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	200	0.88	0.060	0.0023	0.00086	1.3e-04	9.3e-06
1B - Spray Application - Large Groundboom				0.55	0.0370	0.0014	0.00053	8.0e-05	5.8e-06
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	1.0	80	1.4	0.096	0.0036	0.00137	2.0e-04	1.5e-05
2B - Spray Application - Average Groundboom				0.88	0.0592	0.0023	0.00085	1.3e-04	9.4e-06
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.25	80	0.35	0.024	0.0009	0.00034	5.1e-05	3.7e-06
2B - Spray Application - Average Groundboom				0.22	0.0148	0.0006	0.00021	3.2e-05	2.3e-06
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	40	0.70	0.0480	0.0018	0.00069	1.0e-04	7.5e-06
3B - Spray Application - ATV Groundboom				0.44	0.0296	0.0011	0.00042	6.4e-05	4.7e-06
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.25	350	1.5	0.105	0.0039	0.00150	2.2e-04	1.6e-05
4B - Spray Application - Fixed-Wing Aircraft				ND - Double layer PPE is not worn for aerial application.					
4C - Flag Aerial Applications				1.0	0.0306	0.0025	0.00044	1.2e-04	8.8e-06
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.25	350	1.5	0.105	0.0039	0.00150	2.2e-04	1.6e-05
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	1.0	25	0.4	0.0300	0.0011	0.00043	6.4e-05	4.7e-06
6B - Spray Application - Right of Way Sprayer				7.3	0.098	0.0186	0.00139	8.2e-04	6.0e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	2	3.2	0.0600	0.0082	0.00086	3.7e-04	2.7e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.2	0.0225	0.0031	0.00032	1.4e-04	1.0e-05
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	1.0	40	0.14	0.0680	0.0004	0.00097	5.4e-05	4.0e-06
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	40	0.17	0.0480	0.0004	0.00069	4.6e-05	3.4e-06
9 - Push Type Broadcast Spreader(Load/Apply)	Ornamentals	1.0	5	0.55	0.0375	0.0014	0.00054	8.0e-05	5.9e-06

Notes for this table follow Table B11.

Table B9: Double Layer with PF5 Respirator Worker Oxyfluorfen Exposure and Cancer Risks

Exposure Scenario	Crops	Average Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Lifetime Absorbed Daily Dose (mg/kg/day)[c]	Cancer Risk [d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	200	1.8	0.024	0.0045	0.00034	2.0e-04	1.5e-05
1B - Spray Application - Large Groundboom				1.1	0.0150	0.0028	0.00021	1.3e-04	9.2e-06
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	200	0.9	0.012	0.0023	0.00017	1.0e-04	7.3e-06
1B - Spray Application - Large Groundboom				0.6	0.0075	0.0014	0.00011	6.3e-05	4.6e-06
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	1.0	80	1.4	0.019	0.0036	0.00027	1.6e-04	1.2e-05
2B - Spray Application - Average Groundboom				0.88	0.0120	0.0023	0.00017	1.0e-04	7.3e-06
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.25	80	0.35	0.005	0.0009	0.00007	4.0e-05	2.9e-06
2B - Spray Application - Average Groundboom				0.22	0.0030	0.0006	0.00004	2.5e-05	1.8e-06
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	40	0.7	0.0096	0.0018	0.00014	8.0e-05	5.8e-06
3B - Spray Application - ATV Groundboom				0.4	0.0060	0.0011	0.00009	5.0e-05	3.7e-06
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.25	350	1.5	0.021	0.0039	0.00030	1.7e-04	1.3e-05
4B - Spray Application - Fixed-Wing Aircraft				ND - Double layer PPE is not worn for aerial application.					
4C - Flag Aerial Applications				1.0	0.0061	0.0025	0.00009	1.1e-04	7.7e-06
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.25	350	1.5	0.021	0.0039	0.00030	1.7e-04	1.3e-05
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	1.0	25	0.4	0.0060	0.0011	0.00009	5.0e-05	3.6e-06
6B - Spray Application - Right of Way Sprayer				7.3	0.020	0.0186	0.00028	7.8e-04	5.7e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	2	3.2	0.0120	0.0082	0.00017	3.5e-04	2.5e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.2	0.0045	0.0031	0.00006	1.3e-04	9.5e-06
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	1.0	40	0.14	0.0136	0.0004	0.00019	2.2e-05	1.6e-06
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	40	0.17	0.0096	0.0004	0.00014	2.3e-05	1.7e-06
9 - Push Type Broadcast Spreader(Load/Apply)	Ornamentals	1.0	5	0.55	0.0075	0.0014	0.00011	6.3e-05	4.6e-06

Notes for this table follow Table B11.

Table B10: Double Layer with PF10 Respirator Worker Oxyfluorfen Exposure and Cancer Risks

Exposure Scenario	Crops	Average Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Lifetime Absorbed Daily Dose (mg/kg/day)[c]	Cancer Risk [d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	200	1.8	0.012	0.0045	0.00017	1.9e-04	1.4e-05
1B - Spray Application - Large Groundboom				1.1	0.0074	0.0028	0.00011	1.2e-04	8.8e-06
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	200	0.88	0.0060	0.0023	0.00009	9.8e-05	7.2e-06
1B - Spray Application - Large Groundboom				0.55	0.0037	0.0014	0.00005	6.0e-05	4.4e-06
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	1.0	80	1.40	0.010	0.0036	0.00014	1.5e-04	1.1e-05
2B - Spray Application - Average Groundboom				0.88	0.0059	0.0023	0.00008	9.6e-05	7.1e-06
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.25	80	0.35	0.0024	0.0009	0.00003	3.8e-05	2.8e-06
2B - Spray Application - Average Groundboom				0.22	0.0015	0.0006	0.00002	2.4e-05	1.8e-06
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	40	0.70	0.0048	0.0018	0.00007	7.7e-05	5.6e-06
3B - Spray Application - ATV Groundboom				0.44	0.0030	0.0011	0.00004	4.8e-05	3.5e-06
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.25	350	1.5	0.011	0.0039	0.00015	1.7e-04	1.2e-05
4B - Spray Application - Fixed-Wing Aircraft				ND - Double layer PPE is not worn for aerial application.					
4C - Flag Aerial Applications				1.0	0.0031	0.0025	0.00004	1.0e-04	7.6e-06
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.25	350	1.5	0.011	0.0039	0.00015	1.7e-04	1.2e-05
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	1.0	25	0.4	0.0030	0.0011	0.00004	4.8e-05	3.5e-06
6B - Spray Application - Right of Way Sprayer				7.3	0.010	0.0186	0.00014	7.7e-04	5.7e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	2	3.2	0.0060	0.0082	0.00009	3.4e-04	2.5e-05
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.2	0.0023	0.0031	0.00003	1.3e-04	9.4e-06
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	1.0	40	0.14	0.0068	0.0004	0.00010	1.8e-05	1.3e-06
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	40	0.17	0.0048	0.0004	0.00007	2.1e-05	1.5e-06
9 - Push Type Broadcast Spreader(Load/Apply)	Ornamentals	1.0	5	0.55	0.0038	0.0014	0.00005	6.0e-05	4.4e-06

Notes for this table follow Table B11.

Table B11: Engineering Controls Oxyfluorfen Worker Exposure and Cancer Risks

Exposure Scenario	Crops	Average Application Rate (lb ai/Acre)	Treated Area (Acres/day)	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Lifetime Absorbed Daily Dose (mg/kg/day)[c]	Cancer Risk[d]
				Dermal	Inhalation	Dermal	Inhalation		
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	200	0.86	0.0083	2.2e-03	1.2e-04	9.6e-05	7.0e-06
1B - Spray Application - Large Groundboom				0.50	0.0043	1.3e-03	6.1e-05	5.5e-05	4.1e-06
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	200	0.43	0.0042	1.1e-03	5.9e-05	4.8e-05	3.5e-06
1B - Spray Application - Large Groundboom				0.25	0.0022	6.4e-04	3.1e-05	2.8e-05	2.0e-06
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors, Nursery Trees Mint	1.0	80	0.69	0.0066	1.8e-03	9.5e-05	7.7e-05	5.6e-06
2B - Spray Application - Average Groundboom				0.40	0.0034	1.0e-03	4.9e-05	4.4e-05	3.2e-06
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.25	80	0.17	0.0017	4.4e-04	2.4e-05	1.9e-05	1.4e-06
2B - Spray Application - Average Groundboom				0.10	0.0009	2.6e-04	1.2e-05	1.1e-05	8.1e-07
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	40	0.34	0.0033	8.8e-04	4.7e-05	3.8e-05	2.8e-06
3B - Spray Application - ATV Groundboom				0.20	0.0017	5.1e-04	2.5e-05	2.2e-05	1.6e-06
4A - Mix/Load Liquids for Aerial Application	Fallow beds	0.25	350	0.75	0.0073	1.9e-03	1.0e-04	8.4e-05	6.1e-06
4B - Spray Application - Fixed-Wing Aircraft				See calculations for single layer PPE which assumes a closed cockpit.					
4C - Flag Aerial Applications				0.02	0.0006	5.0e-05	8.8e-06	2.4e-06	1.8e-07
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.25	350	0.75	0.0073	1.9e-03	1.0e-04	8.4e-05	6.1e-06
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Way Areas	1.0	25	0.22	0.0021	5.5e-04	3.0e-05	2.4e-05	1.8e-06
6B - Spray Application - Right of Way Sprayer				No Data for This Scenario					
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	2	No Data for This Scenario					
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	No Data for This Scenario					
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	1.0	40	0.0068	0.0014	1.7e-05	1.9e-05	1.5e-06	1.1e-07
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	40	0.084	0.0088	2.2e-04	1.3e-04	1.4e-05	1.0e-06
9 - Push Type Broadcast Spreader(Load/Apply)	Ornamentals	1.0	5	No Data for This Scenario					

Notes for Tables B7 through B11

a Daily Exposure (mg/day) = Application Rate (lb ai/Acre) * Treated Area (Acre/day) * Unit Exposure Value (mg or µg exposure/ lb ai handled) *[1mg/1000µg (conversion factor if necessary)].
b Absorbed Daily Dose (mg/kg/day) = Daily Exposure (mg/day) * Absorption Factor (0.18 for dermal; 1.0 for inhalation) ÷ Body Weight (70kg).
c Combined Lifetime Averaged Daily Dose (mg/kg/day) = Combined Potential Daily Dose (see note below) * 30 Annual Treatment Days / 365 days per year * 35 years working / 70 year lifespan.
Note - Combined Potential Daily Dose (mg/kg/day) = Dermal Potential Daily Dose (mg/kg/day) + Inhalation Potential Daily Dose (mg/kg/day).

d Carcinogenic Risk = Combined Lifetime Averaged Daily Dose (mg/kg/day) * Q_1^* (mg/kg/day)$^{-1}$. Q_1^* = 0.073 for Oxyfluorfen.
e Airplane pilots are assumed to fly closed cockpit aircraft. Gloves are not worn.

Table B12: Summary of Oxyfluorfen Occupational Exposure Scenarios and Non-Cancer Risks

Exposure Scenario	Crops	Label Application Rate[a] (lbs ai/acre)	Treated Area[b] (acres/day)	Baseline PPE[c] MOE[e] Short	Baseline PPE[c] MOE[e] Intermediate Term	Single Layer without Respirator[d] MOE[e] Short	Single Layer without Respirator[d] MOE[e] Intermediate Term
1A - Mix/Load Liquids - Large Groundboom	Corn	0.75	200	**23**	**28**	2200	2400
1B - Spray Application - Large Groundboom				3700	4600	3700	3900
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.5	200	**34**	**43**	3400	3600
1B - Spray Application - Large Groundboom				5500	6900	5500	5900
2A - Mix/Load Liquids - Average Groundboom	Orchard/Vineyard Floors Nursery Trees Mint	2.0	80	**22**	**27**	2100	2200
2B - Spray Application - Average Groundboom				3450	4300	3500	3700
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.50	80	**86**	**110**	8400	9000
2B - Spray Application - Average Groundboom				14000	17000	14000	15000
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	2.0	40	**43**	**54**	4200	4500
3B - Spray Application - ATV Groundboom				6900	8600	6900	7400
4A - Mix/Load Liquids for Aerial Application	Fallow Beds	0.25	1200	**5.7**	**7.1**	560	600
4B - Spray Application - Aerial				3100	3900	N/A	N/A
4C - Flag Aerial Applications				1300	1600	1200	1300
5 - Mix/Load for Chemigation	Onions, Garlic, Horseradish	0.5	350	**20**	**24**	1900	2100
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Ways	2.0	50	**69**	**86**	6700	7200
6B - Spray Application - Right of Way Sprayer				150	**190**	490	520
7 - Mix/Load/Apply Liquids - Backpack	Conifers	2.0	2	ND	ND	940	1000
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	ND	ND	5000	5300
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	2.0	40	7000	8700	7600	8200
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	2.0	40	7500	9400	9000	9600
9 - Load and Apply Using Broadcast Spreader	Ornamentals	2.0	5	2600	3200	3800	4100

Notes for Table B12:

a Application rates are the maximum values listed on the labels.
b Amounts of acreage treated per day are from the HED Science Advisory Council for Exposure Policy #009 " Standard Values for Daily Acres Treated in Agriculture"
c Baseline PPE - long pants, long sleeved shirt, no gloves, no respirator.
d Single Layer PPE - chemical resistant gloves, long pants, long sleeved shirt, hat and no respirator.
e MOE (unitless) = NOAEL (mg/kg/day) ÷ Combined Absorbed Daily Dose (mg/kg/day). Where NOAEL = 30 mg/kg/day for short-term and 32 mg/kg/day for intermediate-term exposures. A Margin of Exposure (MOE) of 100 or greater is acceptable for short term exposures. A MOE of 300 is acceptable for intermediate term exposures.

Table B13: Summary of Oxyfluorfen Cancer Risks for Custom Applicators (30 Exposure Days per Year)

Exposure Scenario	Crops	Average Application Rate[a] (lb ai/Acre)	Treated Area[b] (Acres/day)	Single Layer[c] Cancer Risk[h]	Double Layer [d] Cancer Risk[h]	Double Layer PF5[e] Cancer Risk[h]	Double Layer PF10[f] Cancer Risk[h]	Engineering Controls[g] Cancer Risk[h]
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	200	2.3e-05	1.9e-05	1.5e-05	1.4e-05	7.0e-06
1B - Spray Application - Large Groundboom				1.4e-05	1.2e-05	9.2e-06	8.8e-06	4.1e-06
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	200	1.1e-05	9.3e-06	7.3e-05	7.2e-06	3.5e-06
1B - Spray Application - Large Groundboom				7.0e-06	5.8e-06	4.6e-06	4.4e-06	2.0e-06
2A - Mix/Load Liquids - Average Groundboom	Orchards/Vineyards Nursery Trees Mint	1.0	80	1.8e-05	1.5e-05	1.2e-05	1.1e-05	5.6e-06
2B - Spray Application - Average Groundboom				1.1e-05	9.4e-06	7.3e-06	7.1e-06	3.2e-06
2A - Mix/Load Liquids - Average Groundboom	Onions, Brassica	0.25	80	4.6e-06	3.7e-06	2.9e-06	2.8e-06	1.4e-06
2B - Spray Application - Average Groundboom				2.8e-06	2.3e-06	1.8e-06	1.8e-06	8.1e-07
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	40	9.2e-06	7.5e-06	5.8e-06	5.6e-06	2.8e-06
3B - Spray Application - ATV Groundboom				5.6e-06	4.7e-06	3.7e-06	3.5e-06	1.6e-06
4A - Mix/Load Liquids for Aerial Application	Fallow Fields	0.25	350	2.0e-05	1.6e-05	1.3e-05	1.2e-05	6.1e-06
4B - Spray Application - Aerial				3.6e-06	N/A	N/A	N/A	N/A
4C - Flag Aerial Applications				9.4e-06	8.8e-06	7.7e-06	7.6e-06	1.8e-07
5 - Chemigation	Onions, Garlic, Horseradish	0.25	350	2.0e-05	1.6e-05	1.3e-05	1.2e-05	6.1e-06
6A - Mix/Load Liquids - Right of Way Sprayer	Right of Ways	1.0	50	5.7e-05	4.7e-06	3.6e-06	3.5e-06	1.8e-06
6B - Spray Application - Right of Way Sprayer				8.0e-05	6.0e-05	5.7e-05	5.7e-05	ND
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	2	4.1e-05	2.7e-05	2.5e-05	2.5e-05	ND
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	2	1.5e-05	1.0e-05	9.5e-06	9.4e-06	ND
8A - Tractor Drawn Broadcast Spreader - Load	Ornamentals	1.0	40	5.1e-06	4.0e-06	1.6e-06	1.3e-06	1.1e-07
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	40	4.3e-06	3.4e-06	1.7e-06	1.5e-06	1.0e-06
9 - Load and Apply Using Broadcast Spreader	Ornamentals	1.0	5	1.0e-05	5.9e-06	4.6e-06	4.4e-06	ND

Table B14: Summary of Oxyfluorfen Cancer Risks for Private Growers (5 or 10 Exposure Days per Year)

Exposure Scenario	Crops	Average Application Rate[a] (lb ai/Acre)	Annual Treatment Days	Treated Area[b] (Acres/day)	Single Layer [c] Cancer Risk[h]	Double Layer[d] Cancer Risk[h]	Double Layer PF5[e] Cancer Risk[h]	Double Layer PF10[f] Cancer Risk[h]	Engineering Controls[g] Cancer Risk[h]
1A - Mix/Load Liquids - Large Groundboom	Corn	0.5	5	200	3.8e-06	3.2e-06	2.5e-06	2.3e-06	1.2e-06
1B - Spray Application - Large Groundboom					2.3e-06	2.0e-06	1.5e-06	1.5e-06	6.8e-07
1A - Mix/Load Liquids - Large Groundboom	Cotton, Soybeans	0.25	5	200	1.8e-06	1.6e-06	1.2e-06	1.2e-06	5.8e-07
1B - Spray Application - Large Groundboom					1.2e-06	9.7e-07	7.7e-07	7.3e-07	3.3e-07
2A - Mix/Load Liquids - Average Groundboom	Orchards/Vineyards Nursery Trees Mint	1.0	5	80	3.0e-06	2.5e-06	2.0e-06	1.8e-06	9.3e-07
2B - Spray Application - Average Groundboom					1.8e-06	1.6e-06	1.2e-06	1.2e-06	5.3e-07
2A - Mix/Load Liquids - Average Groundboom	Onion, Brassica	0.25	5	80	7.7e-07	6.2e-07	4.8e-07	4.7e-07	2.3e-07
2B - Spray Application - Average Groundboom					4.7e-07	3.8e-07	3.0e-07	3.0e-07	1.4e-07
3A - Mix/Load Liquids - ATV Groundboom	Artichokes	1.0	5	40	1.5e-06	1.3e-06	9.7e-07	9.3e-07	4.7e-07
3B - Spray Application - ATV Groundboom					9.3e-07	7.8e-07	6.2e-07	5.8e-07	2.7e-07
4A - Mix/Load Liquids for Aerial Application 4B - Spray Application - Aerial 4C - Flag Aerial Applications	Fallow Fields	ND - Aerial application is rarely done by private growers because of the high cost of maintaining an airplane. It is usually done by custom applicators.							
5 - Mix/Load Liquids for Chemigation	Onions, Garlic, Horseradish	0.25	5	350	3.3e-06	2.7e-06	2.2e-06	2.0e-06	1.0e-06
6A - Mix/Load Liquids - Right of Way Sprayer 6B - Spray Application - Right of Way Sprayer	Right of Ways	Right of Way of sprayers are not typically used by private growers. Are typically used by state transportation department employees or contractors.							
7 - Mix/Load/Apply Liquids - Backpack	Conifers	1.0	5	2	6.8e-06	4.5e-06	4.2e-06	4.2e-06	ND
7 - Mix/Load/Apply Liquids - Backpack	Conifers	0.375	5	2	2.5e-06	1.7e-06	1.6e-06	1.6e-06	ND
8A - Tractor Drawn Broadcast Spreader - Load	Conifers	1.0	10	40	1.7e-06	1.3e-06	5.3e-07	4.3e-07	3.7e-08
8B - Tractor Drawn Broadcast Spreader - Apply	Ornamentals	1.0	10	40	1.4e-06	1.1e-06	5.7e-07	5.0e-07	3.3e-07
9 - Load and Apply Using Broadcast Spreader	Ornamentals	1.0	10	5	3.3e-06	2.0e-06	1.5e-06	1.5e-06	ND

Notes for Tables B13 and B14:

a Application rates are the average values found in the Quantitative Use Report for Oxyfluorfen of June 5, 2001.
b Amounts of acreage treated per day are from the HED Science Advisory Council for Exposure Policy #009 " Standard Values for Daily Acres Treated in Agriculture”
c Single Layer - chemical resistant gloves, long pants, long sleeved shirt, hat and no respirator.
d Double Layer - coveralls over single layer clothing, chemical resistant gloves .
e Double Layer PF5 - Same as above with a PF5 Dust/mist respirator or dust mask
• Double Layer PF10 - Same as above with a PF10 half face cartridge respirator
g Engineering Controls - Includes closed mixing/loading and/or enclosed cab application
h Carcinogenic Risk = Lifetime Averaged Daily Dose (mg/kg/day) * Q_1^* (mg/kg/day)$^{-1}$. Q_1^* = 0.0732 for Oxyfluorfen.

APPENDIX C

OXYFLUORFEN
POST APPLICATION WORKER
EXPOSURE AND RISK ASSESSMENT TABLES

Table C1 - Summary of Oxyfluorfen Worker Post Application Risks (Non-Cancer Short and Intermediate Term)

Crop Type (Specific Crops)	Input Parameters Used	Application Rate[3] Maximum/Average (lbs ai/acre)	Post Application Exposures	Transfer Coefficient (cm^2/hr)	Short Term MOE on DAT 0	DAT When Short Term MOE >100	Intermediate Term MOE on DAT 0	DAT When Intermediate Term MOE >300
Bulb Vegetables (Garlic, Onions)	Default[1]	0.5/0.25	Irrigation, scouting, weeding	300	3700	0	9200	0
Tree Seedlings, Conifer	Default[1]	1.0/0.5	Irrigation, scouting, hand weeding escaped weeds	1000	560	0	1400	0
Tree Seedlings, Conifer	Study Data[2]	1.0/0.5	Irrigation, scouting, hand weeding escaped weeds	1000	560	0	1400	0
Trees, Conifers	Default[1]	2.0/1.0	Irrigation, scouting Shearing	1000 3000	280 93	0 1	690 230	0 3
Trees, Conifers	Default[1]	0.375	Irrigation, scouting Shearing	1000 3000	1500 500	0 0	1800 620	0 0
Trees, Conifers	Study Data[2]	2.0/1.0	Irrigation, scouting Shearing	1000 3000	280 93	0 1	690 230	0 1
Trees, Conifers	Study Data[2]	0.375	Irrigation, scouting Shearing	1000 3000	1500 500	0 0	1800 620	0 0

1. Default parameters are 20% of amount applied deposits on the foliage and dissipates at a rate of 10% per day.
2. Data from MRID 420983-01 indicates dissipation rates of 90% for day 0 to day 1 and 34% after day 1.
3. Maximum label rates are used for short term risks and average rates are used for intermediate term risks.

Table C2 - Summary of Oxyfluorfen Worker Post Application Cancer Risks (30 days exposure per year)

Crop Type (Specific Crops)	Input Parameters Used	Application Rate (lbs ai/acre)	Activity	Transfer Coefficient (cm^2/hr)	Cancer Risk on DAT 0	DAT When Cancer Risk <1.0e-04	DAT When Cancer Risk <1.0e-06
Bulb Vegetables(Garlic, Onions)	Default	0.25	Irrigation, scouting, weeding	300	1.0e-05	0	23
Tree Seedlings, Conifer	Default	0.5	Irrigation, scouting, hand weeding escaped weeds	1000	6.9e-05	0	41
Tree Seedlings, Conifer	Study Data	0.5	Irrigation, scouting, hand weeding escaped weeds	1000	6.9e-05	0	6
Trees, Conifer	Default	1.0	Irrigation, scouting Shearing	1000 3000	1.4e-04 4.2e-04	4 14	47 58
Trees, Conifer	Default	0.375	Irrigation, scouting Shearing	1000 3000	5.2e-05 1.6e-04	0 5	38 48
Trees, Conifer	Study Data	1.0	Irrigation, scouting Shearing	1000 3000	1.4e-04 4.2e-04	1 1	8 11
Trees, Conifer	Study Data	0.375	Irrigation, scouting Shearing	1000 3000	5.2e-05 1.6e-04	0 1	6 8

Table C3 - Summary of Private Grower Oxyfluorfen Post Application Cancer Risks (10 days exposure per year)

Crop Type (Specific Crops)	Input Parameters	Application Rate (lbs ai/acre)	Activity	Transfer Coefficient (cm^2/hr)	Cancer Risk on DAT 0	DAT When Cancer Risk <1.0e-04	DAT When Cancer Risk <1.0e-06
Bulb Vegetables (Garlic, Onions)	Default	0.25	Irrigation, scouting, weeding	300	3.5e-06	0	12
Tree Seedlings, Conifer	Default	0.5	Irrigation, scouting, hand weeding escaped weeds	1000	2.3e-05	0	30
Tree Seedlings, Conifer	Study Data	0.5	Irrigation, scouting, hand weeding escaped weeds	1000	2.3e-05	0	4
Trees, Conifer	Default	1.0	Irrigation, scouting Shearing	1000 3000	4.6e-05 1.4e-04	0 4	37 47
Trees, Conifer	Default	0.375	Irrigation, scouting Shearing	1000 3000	1.7e-05 5.2e-05	0 0	28 38
Trees, Conifer	Study Data	1.0	Irrigation, scouting Shearing	1000 3000	4.6e-05 1.4e-04	0 1	5 8
Trees, Conifer	Study Data	0.375	Irrigation, scouting Shearing	1000 3000	1.7e-05 5.2e-05	0 0	3 6

APPENDIX D

OXYFLUORFEN
RESIDENTIAL HANDLER
EXPOSURE AND RISK
ASSESSMENT TABLES

Table D1: Numerical Inputs for Residential Applicator Exposure to Oxyfluorfen

Exposure Scenario	Area Treated (SF)	Amount of Oxyfluorfen Used	Application rate	Unit Exposure Values	
				Dermal[d] (mg/lb ai handled)	Inhalation[e] (μg/lb ai handled)
(1) Spot Treat Weeds Using Low Pressure Tank Sprayer (Kleenup Super Edger)[a]	300	0.022 lb Ai	0.022 lb ai/ 300 SF	38	30
(2) Spot Treat Weeds Using Mix Your Own Sprinkler Can[b] (Ortho Groundclear Triox)	200	0.041 lb Ai	0.041 lb Ai/ 200 SF	11	16
(3) Spot Treat Weeds Using RTU Invert Jug[c] (Ortho Groundclear SuperEdger)	200	0.022 lb Ai	0.022 lb Ai/ 200 SF	2.6	11
(4) Spot Treat Weeds Using a RTU Trigger Pump Sprayer (Kleen up Super Edger)	200	0.022 lb Ai	0.022 lb ai/ 200 SF	53	67

a. Using one gallon of pre-mixed solution which contains 0.25% Oxyfluorfen or 0.022 lbs Oxyfluorfen per gallon..
b. Concentrate containing 0.70% Oxyfluorfen. 2.67 quarts of concentrate are mixed with 3.0 gallons of water to treat 200 SF.
c. The RTU Invert Jug has a built-in applicator which is activated by removing the cap and inverting the jug. One gallon covers 200 SF.
d. Dermal unit exposure represents an individual's estimated exposure while wearing short pants, short sleeved shirt and no gloves.
e. Inhalation unit exposure represents no use of a respirator.

Table D2: Exposure and Non-Cancer Risks for Residential Application of Oxyfluorfen

Exposure Scenario	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Absorbed Daily Dose (mg/kg/day)[c]	Combined MOE[d,e]
	Dermal	Inhalation	Dermal	Inhalation		
(1) Spot Treat Weeds Using Low Pressure Tank Sprayer	0.84	6.6e-04	2.5e-03	1.1e-05	2.5e-03	11909
(2) Spot Treat Weeds Using Mix Your Own Sprinkler Can	0.45	6.6e-04	1.4e-03	1.1e-05	1.4e-03	21995
(3) Spot Treat Weeds Using RTU Invert Jug	0.057	2.4e-04	1.7e-04	4.0e-06	1.8e-04	170810
(4) Spot Treat Weeds Using a RTU Trigger Pump Sprayer	1.2	1.5e-03	3.5e-03	2.5e-05	3.5e-03	8517

a. Daily Exposure = Amount of Ai Used * Unit Exposure Value * Conversion Factor (if necessary)
(mg/day) (lb/day) (mg or *u*g/lb ai handled) (1 mg/1000 ug)

b. Absorbed Daily Dose = Daily Exposure * Absorption Factor (0.18 for dermal, 1.0 for inhalation) / Body Weight (60 kg)
(mg/kg/day) (mg/day)

c. Combined Absorbed Daily Dose (CADD) = Dermal Absorbed Daily Dose + Inhalation Absorbed Daily Dose
(mg/kg/day) (mg/kg/day) (mg/kg/day)

d. MOE = NOAEL (mg/kg/day)/CADD (mg/kg/day). Where NOAEL = 30 mg/kg/day for short term exposures.

e. A Margin of Exposure (MOE) of 100 or greater is acceptable for Oxyfluorfen.

Table D3: Exposure and Cancer Risks for Residential Application of Oxyfluorfen (Assuming two treatment days of exposure per year)

Exposure Scenario	Daily Exposure (mg/day)[a]		Absorbed Daily Dose (mg/kg/day)[b]		Combined Absorbed Daily Dose (mg/kg/day)[c]	LADD (mg/kg/day)[d]	Cancer Risk[e,f]
	Dermal	Inhalation	Dermal	Inhalation			
(1) Spot Treat Weeds Using Low Pressure Tank Sprayer	0.84	0.00066	2.2e-03	9.4e-06	2.2e-03	8.5e-06	6.2e-07
(2) Spot Treat Weeds Using Mix Your Own Sprinkler Can	0.45	0.00066	1.2e-03	9.4e-06	1.2e-03	4.6e-06	3.3e-07
(3) Spot Treat Weeds Using RTU Invert Jug	0.057	0.00024	1.5e-04	3.5e-06	1.5e-04	5.9e-07	4.3e-08
(4) Spot Treat Weeds Using RTU Trigger Pump Sprayer	1.2	0.00147	3.0e-03	2.1e-05	3.0e-03	1.2e-05	8.7e-07

a. Same as in Table D2 above.

b. Same as in Table D2 except that a body weight of 70 kg was used instead of 60 kg.

c. Combined Absorbed Daily Dose (CADD) = Dermal Absorbed Daily Dose + Inhalation Absorbed Daily Dose
(mg/kg/day) (mg/kg/day) (mg/kg/day)

d. Lifetime Averaged Daily Dose (LADD) = CADD * (2 Annual Treatment Days/365 days per year)*(50 years exposure/70 year lifespan)
(mg/kg/day)

e. Cancer Risk = LADD (mg/kg/day)*Q_1* $(mg/kg/day)^{-1}$. Q_1* = 0.0732 for Oxyfluorfen.

f. Cancer risks less than 1.0 X 10^{-6} are below HED's level of concern.

Table D4: Residential Exposure Scenario Description for the Use of Oxyfluorfen

Exposure Scenario	Data Source	Operation Sampled	Data Confidence[A]
(1) Spot Treat Weeds Using Low Pressure Tank Sprayer	MRID 444598-01	Residential Applicator Hand Held Pump Spray	High Confidence: Dermal Replicates = 20, A grade. Hand replicates = 20, A grade. Inhalation = 40 replicates, A grade
(2) Spot Treat Weeds Using Mix Your Own Sprinkler Can	ORETF[a] Study # OMA004	Residential Applicator, Hose End Sprayer, Mix your own	High Confidence: Dermal Replicates = 30, A grade. Hand replicates = 30, A grade. Inhalation = 30 replicates, A grade
(3) Spot Treat Weeds Using RTU Invert Jug		Residential Applicator, Hose End Sprayer, Ready to Use (no mixing)	High Confidence: Dermal Replicates = 30, A grade. Hand replicates = 30, A grade. Inhalation = 30 replicates, A grade
(4) Spot Treat Weeds Using RTU Trigger Sprayer	MRID 444598-01	Residential Applicator, RTU Trigger Sprayer	See above for scenario #1.

a. Occupational Residential Exposure Task Force

Appendix E

Residue Chemistry Tolerance Reassessment

Table 1. Tolerance Reassessment Summary for Oxyfluorfen.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.381 (a):			
Almond hulls	0.1	0.1	*[Almond, hulls]*
Artichokes	0.05	0.05	*[Artichoke, globe]*
Avocados	0.05	0.05	*[Avocado]*
Bananas (including plantain)	0.05	TBD [1]	*[Banana (including plantain)]*
Broccoli	0.05	0.05	The registrant may wish to propose a crop group tolerance of 0.05 ppm for Head and stem Brassica subgroup.
Cabbage	0.05	0.05	
Cauliflower	0.05	0.05	
Cattle, fat	0.05	0.01	
Cattle, mbyp	0.05	0.01	
Cattle, meat	0.05	0.01	
Cocoa beans	0.05	TBD [1]	*[Cacao bean]*
Coffee	0.05	0.05	*[Coffee bean, green]*
Corn, grain	0.05	0.05	*[Corn, field, grain]*
Cottonseed	0.05	0.05	*[Cotton, undelinted seed]*
Dates	0.05	0.05	*[Date]*
Eggs	0.05	0.03	
Feijoa	0.05	0.05	*[Feijoa (pineapple guava)]*
Figs	0.05	0.05	*[Fig]*
Garlic	--	0.05	
Goat, fat	0.05	0.01	
Goat, mbyp	0.05	0.01	
Goat, meat	0.05	0.01	
Grapes	0.05	0.05	*[Grape]*
Hogs, fat	0.05	0.01	
Hogs, mbyp	0.05	0.01	
Hogs, meat	0.05	0.01	
Horseradish	0.05	0.05	
Horses, fat	0.05	0.01	
Horses, mbyp	0.05	0.01	
Horses, meat	0.05	0.01	
Kiwifruit	0.05	0.05	
Olives	0.05	0.05	*[Olive]*
Onions (dry bulb)	0.05	0.05	*[Onion, dry bulb (only)]*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Milk	0.05	0.01	
Mint hay (peppermint and spearmint)	0.1	0.05	Separate tolerances should be established, each at 0.05 ppm for: *[Peppermint, tops]* *[Spearmint, tops]*
Persimmons	0.05	0.05	*[Persimmon]*
Pistachios	0.05	0.05	*[Pistachio]*
Pome fruits group	0.05	0.05	*[Fruit, Pome, Group]*
Pomegranates	0.05	0.05	*[Pomegranate]*
Poultry, fat	0.05	0.2	
Poultry, mbyp	0.05	0.01	
Poultry, meat	0.05	0.01	
Sheep, fat	0.05	0.01	
Sheep, mbyp	0.05	0.01	
Sheep, meat	0.05	0.01	
Soybeans	0.05	0.05	*[Soybean]*
Stone fruits group	0.05	0.05	*[Fruits, Stone, Group]*
Tree nuts group (except almond hulls)	0.05	0.05	*[Nuts, Tree, Group]*
Tolerances To Be Proposed Under 40 CFR §180.381 (a):			
Cotton, gin byproducts	None	TBD [1]	New RAC according to Table 1 (OPPTS 860.1000).
Soybean forage	None	TBD [1]	A feeding restriction may be established in lieu of proposing tolerances.
Soybean hay	None	TBD [1]	
Tolerances Listed Under 40 CFR §180.381 (b):			
Strawberries	0.05	0.05	*[Strawberry]*
Tolerances Listed Under 40 CFR §180.381 (c):			
Blackberry	0.05	0.05	Recently established under PP#5E04429 (60 FR 62330, 12/6/95)
Garbanzo beans	0.05	0.05	*[Chickpea (bean, garbanzo)]*
Guava	0.05	0.05	
Papaya	0.05	0.05	
Raspberry	0.05	0.05	Recently established under PP#5E04429 (60 FR 62330, 12/6/95)
Taro (corms and leaves)	0.05	0.05	Separate tolerances should be established, each at 0.05 ppm for: *[Taro, corm]*, *[Taro, foliage]*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances To Be Proposed Under 40 CFR §180.381 (c)			
Grass Forage, Grass Hay, and Grass Seed Screenings	None	0.05	Separate tolerances should be established, each at 0.05 ppm for grass forage, grass hay and grass seed screenings

[1]TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because residue data are required.